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THIRD READING

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Bill No: AB 365  
Author: Aguiar-Curry (D)  
Amended: 3/15/23 in Assembly  
Vote: 21

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SENATE HEALTH COMMITTEE: 12-0, 6/21/23

AYES: Eggman, Nguyen, Glazer, Gonzalez, Grove, Hurtado, Limón, Menjivar,  
Roth, Rubio, Wahab, Wiener

SENATE APPROPRIATIONS COMMITTEE: Senate Rule 28.8

ASSEMBLY FLOOR: 80-0, 5/31/23 - See last page for vote

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**SUBJECT:** Medi-Cal: diabetes management

**SOURCE:** American Diabetes Association

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**DIGEST:** This bill adds continuous glucose monitors (CGMs) as a benefit in the Medi-Cal schedule of benefits. This bill requires the Department of Health Care Services to review and update as appropriate the coverage policies for CGMs by July 1, 2024.

**ANALYSIS:**

Existing law:

- 1) Establishes the Medi-Cal program, administered by the Department of Health Care Services (DHCS), under which low-income individuals are eligible for medical coverage. [WIC §14000, et seq.]
- 2) Establishes a schedule of benefits for the Medi-Cal program, which includes federally required and optional Medicaid benefits, including durable medical equipment (DME) and medical supplies, and coverage of diabetic test supplies when provided by a pharmacy. [WIC §14132]

This bill:

- 1) Adds CGMs and related supplies required for use with those monitors to the Medi-Cal schedule of benefits for the treatment of diabetes when medically necessary, subject to utilization controls.
- 2) Requires DHCS to review, and update, as appropriate, coverage policies for CGMs by July 1, 2024. Requires DHCS to consider current evidence-based clinical guidelines and coverage policies of other payers for purposes of this review.
- 3) Authorizes DHCS to require the manufacturer of a CGM to enter into a rebate agreement with DHCS.
- 4) Conditions implementation of this bill upon the receipt of federal approval and federal financial participation.
- 5) Makes legislative findings that one in seven adults, or approximately four million people in California have diabetes; California has the highest level in the nation of new diabetes cases annually; diabetes is the seventh leading cause of death in California; and diabetes is the leading cause of cardiovascular disease, adult blindness, kidney failure, and amputation of the lower extremities.

## Comments

- 1) *Author's statement.* According to the author, three million Californians, or around one in seven adults, have diabetes. Among U.S. states, California has the highest level of new cases of diabetes annually. Additionally, the number of persons with diabetes in California has increased 32% in 10 years. With this increase in diabetes, CGMs provide significant, potentially life-changing benefits for diabetes management and avoid or delay serious co-morbidities, hospitalizations and even death. DHCS's current Medi-Cal coverage of CGMs unnecessarily restricts access to CGMs to people with certain types of diabetes. This bill codifies Medi-Cal coverage of CGMs and requires DHCS to review and update their coverage policies for CGMs while considering current medical standards of care.
- 2) *Diabetes in California.* According to the California Department of Public Health (CDPH), diabetes is the seventh leading cause of death in California, with African Americans, Native Americans, and Latinos dying at greater rates than white or Asian American/Pacific Islanders. People who are lower income are also more likely to have diabetes: over 10% of adults with family incomes

below 200% of the federal poverty level (FPL) have Type 2 diabetes, while 6% of adults with family incomes above 300% of FPL have Type 2 diabetes. Not only are low-income and people of color more impacted by the disease itself, they experience far worse complications due to inadequate access to health care. For example, a Kaiser Health News analysis found that in California, where doctors performed more than 82,000 diabetic amputations from 2011 to 2017, people who were black or Latino were more than twice as likely as non-Hispanic whites to undergo amputations related to diabetes. A 2014 study by UCLA researchers found that people with diabetes in poorer neighborhoods in Los Angeles County were twice as likely to have a foot or leg amputated than those in wealthier areas. The difference was more than tenfold in some parts of the county. Complications from diabetes also lead to end stage renal disease, ophthalmic complications including blindness, and put individuals at risk of additional comorbidities such as cardiovascular disease, hypertension, high blood cholesterol and arthritis. Management of diabetes is important in keeping these other conditions under control as well.

- 3) *Medi-Cal coverage of CGMs.* In 2021, funding for Medi-Cal coverage for CGMs for adults with Type 1 diabetes starting in January of 2022 was included in the Budget Act of 2021 (AB 128, Ting, Chapter 21, Statutes of 2021), though CGMs were not specifically enumerated in the Act or accompanying trailer bill language. The following year, the health trailer bill, SB 184 (Committee on Budget and Fiscal Review, Chapter 47, Statutes of 2022), recognized CGMs as a covered benefit in that it specifically exempted CGMs from payment reductions that apply to other benefits and services.

A CGM is a device used to monitor blood glucose on a continual basis for people with diabetes who require insulin. Currently approved CGMs use an enzymatic technology which reacts with glucose molecules and require a wearer to have a sensor placed under the skin, a transmitter on the body, and a receiver device that reads the signal. These are generally a replacement for traditional finger prick testing that people with diabetes who use insulin use throughout the day. Several studies have demonstrated that CGMs reduce the time wearers spend in hypoglycemia and appears to lower hemoglobin A1c levels, particularly when used by individuals with poorly controlled diabetes, particularly if a CGM is used together with an integrated insulin pump. Like many medically necessary specific devices, supplies, and services, CGMs are not specifically listed in state law as a Medi-Cal benefit, though DHCS describes when Medi-Cal will cover CGMs in the Medi-Cal provider manual.

- 4) *Current Medi-Cal requirements for CGMs.* According to the Medi-Cal provider manual, Medi-Cal recipients must meet *all* of the following criteria in order to have a CGM:
- a) Is under the immediate and ongoing care of, and the CGM is ordered by, an endocrinologist or a healthcare practitioner with experience in diabetes management and continuous subcutaneous insulin infusion therapy;
  - b) Has Type 1 insulin-dependent diabetes;
  - c) Is on an insulin treatment plan that requires three or more daily injections of insulin or a continuous subcutaneous insulin infusion pump;
  - d) Is on an insulin treatment regimen that requires frequent adjustments of insulin dosing on the basis of self-monitoring blood glucose testing an average of three times or more per day or CGM testing results;
  - e) Is within the manufacturer's recommendations for appropriate age range;
  - f) Has completed a comprehensive diabetes education program or diabetes prevention program within the last 12 months;
  - g) The beneficiary and/or caregiver demonstrates the ability to understand and appropriately respond to information displayed on a CGM receiver;
  - h) The beneficiary and/or caregiver demonstrates a high level of motivation to achieve tighter glucose control and competency to accurately use the CGM system and comply with recommended use and as instructed in the manufacturers' current labeling;
  - i) The beneficiary and/or caregiver agrees that the beneficiary will wear the CGM at least five days per week of use or 20 days of use per month;
  - j) Has been seen and evaluated by an endocrinologist or a healthcare practitioner with experience in diabetes management and continuous subcutaneous insulin infusion therapy at least every six months, either in person or virtually through video or telephone conferencing, to evaluate their diabetes control and determines that criteria above have been met and documented;
  - k) The initial prior authorization period must not exceed six months; and
  - l) An average blood sugar level value measured within six months must be documented on the prior authorization request.

For therapeutic CGM and beneficiaries residing in a long-term care facility setting, clinical justification must be included and demonstrate why traditional use of a Self-Monitoring Blood Glucose Test System administered by licensed care staff and continuous medical support reimbursed by state or federal resources does not meet the patient's clinical needs.

By definition, this criteria excludes recipients with Type 2 and gestational diabetes, as well as many patients with Type 1 diabetes with inadequate access to specialty care. CGM has been recognized as the standard of care for all patients who are able to use the devices with Type 1 diabetes by various professional societies, including the Endocrine Society, American Diabetes Association, and the American Association of Clinical Endocrinology, and can be the standard of care for some forms of Type 2 or gestational diabetes depending on how frequently insulin injections are needed and other individual patient factors.

**FISCAL EFFECT:** Appropriation: No Fiscal Com.: Yes Local: No

**SUPPORT:** (Verified 8/21/23)

American Diabetes Association (source)  
Biocom California  
California Academy of Family Physicians  
California Black Health Network  
California Chapter of the American College of Cardiology  
California Chronic Care Coalition  
CaliforniaHealth+ Advocates  
California Life Sciences  
Children's Specialty Care Coalition  
County Health Executives Association of California  
Diabetes Patient Advocacy Coalition  
Western Center on Law & Poverty

**OPPOSITION:** (Verified 8/21/23)

Department of Finance

**ARGUMENTS IN SUPPORT:** This bill's sponsor, the American Diabetes Association (ADA), and several other supporters write that Medi-Cal's current utilization criteria for CGMs does not appear to be based on scientific guidelines, and instead are over burdensome and will unnecessarily act as a barrier to potentially life-saving technology. For people living with diabetes, CGMs provide significant benefits for diabetes management because provide greater detail than traditional blood glucose meters, which can aid in achieving glycemic targets and help providers and patients determine effective insulin dosing. CGMs continuously monitor blood glucose levels and use alarms and alerts to inform patients when blood glucose levels are exceeding or falling below specified thresholds. CGM systems provides information about the direction and magnitude of blood glucose

levels, and as a result, these devices facilitate the making of optimal treatment decisions by and for individuals with diabetes. They also point to a 2015 DHCS report, which found that Medi-Cal program associated with adult individuals treated for diabetes totaled \$3.6 billion, which is approximately 14% of total spending on non-dual eligible adults. Additionally, an ADA study shows that individuals enrolled in Medicaid are two to five times less likely to use a CGM than those with a commercial health plan and that states with higher rates of whites enrolled in their Medicaid programs have higher CGM use than states with higher rates of Black enrollees. Finally, they point out that during the COVID-19 pandemic, approximately 40% of the COVID-19 deaths occurred among people with diabetes.

**ARGUMENTS IN OPPOSITION:** The Department of Finance (DOF) writes in opposition to this bill because stating it is duplicative of current practice. According to DOF, while this bill conforms with current DHCS policy on product category review processes and does not add another benefit (given that CGMs are already covered in the Medi-Cal program), they note that codifying these administrative policies into statute would minimize DHCS' administrative flexibility to respond and adapt to potential changes in federal requirements or technology. DOF notes that SB 184 (Committee on Budget and Fiscal Review, Chapter 47, Statutes of 2022), the Health Omnibus Trailer Bill, specifically exempted CGMs from payment reductions. DOF also states that this bill does not result in significant costs for the Medi-Cal program.

ASSEMBLY FLOOR: 80-0, 5/31/23

AYES: Addis, Aguiar-Curry, Alanis, Alvarez, Arambula, Bains, Bauer-Kahan, Bennett, Berman, Boerner, Bonta, Bryan, Calderon, Juan Carrillo, Wendy Carrillo, Cervantes, Chen, Connolly, Megan Dahle, Davies, Dixon, Essayli, Flora, Mike Fong, Vince Fong, Friedman, Gabriel, Gallagher, Garcia, Gipson, Grayson, Haney, Hart, Holden, Hoover, Irwin, Jackson, Jones-Sawyer, Kalra, Lackey, Lee, Low, Lowenthal, Maienschein, Mathis, McCarty, McKinnor, Muratsuchi, Stephanie Nguyen, Ortega, Pacheco, Papan, Jim Patterson, Joe Patterson, Pellerin, Petrie-Norris, Quirk-Silva, Ramos, Reyes, Luz Rivas, Robert Rivas, Rodriguez, Blanca Rubio, Sanchez, Santiago, Schiavo, Soria, Ta, Ting, Valencia, Villapudua, Waldron, Wallis, Ward, Weber, Wicks, Wilson, Wood, Zbur, Rendon

Prepared by: Jen Flory / HEALTH / (916) 651-4111  
8/24/23 11:11:43

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