

California Health Benefits Review Program

Analysis of California Assembly Bill 447 Continuous Glucose Monitors

A Report to the 2017-2018 California State Legislature

April 12, 2017



Key Findings:

Analysis of California Assembly Bill 447 Continuous Glucose Monitors



Summary to the 2017-2018 California State Legislature, April 12, 2017

AT A GLANCE

The version of California Assembly Bill (AB) 447 analyzed by CHBRP would require Medi-Cal coverage of continuous glucose monitors (CGMs), as medically necessary, for the maintenance and treatment of type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM), and gestational diabetes mellitus (GDM).

1. CHBRP estimates that AB 447 would affect the health insurance of 10.8 million beneficiaries in Medi-Cal Managed Care Plans, the Medi-Cal Fee-for-Service (FFS) program, and Medi-Cal County Organized Health Systems (COHS).
2. **Benefit coverage.** Approximately 91% of beneficiaries enrolled in Medi-Cal Managed Care and COHS and 0% of those receiving benefits through the FFS program have coverage for CGMs. AB 447 would not require coverage for a new state benefit mandate within the state-regulated private market and therefore will not exceed the definition of EHBs in California.
3. **Utilization.** Utilization of CGMs is expected to increase from 3.979 per 1,000 Medi-Cal beneficiaries to 4.386 per 1,000 Medi-Cal beneficiaries.
4. **Expenditures.** Expenditures will increase by \$2,105,000 for Medi-Cal Managed Care Plans, \$385,000 for COHS, and unknown amount for the FFS program should AB 447 be enacted.
5. **Medical effectiveness.**
 - a. **T1DM.** There is limited evidence that use of real-time CGMs for patients with T1DM are effective. There is a preponderance of evidence that the use of retrospective CGMs for patients with T1DM are not effective
 - b. **T2DM.** There is limited evidence that use of retrospective and real-time CGMs are not effective for patients with T2DM.
 - c. **GDM.** Evidence is limited for retrospective CGM and insufficient for real-time CGM for improving glucose levels or maternal pregnancy or infant health outcomes for women with GDM.

AT A GLANCE, continued

6. **Public health.** CHBRP projects that the 2,255 additional CGM users, who use CGMs consistently, would see improvements in glycemic control as compared with self-monitoring blood glucose testing alone.
7. **Long-term impacts.** Due to the lack of evidence regarding long-term health outcomes associated with CGM use (i.e., reductions in stroke, kidney disease, amputations, blindness, etc.), the long-term public health impact of AB 447 is unknown.

CONTEXT

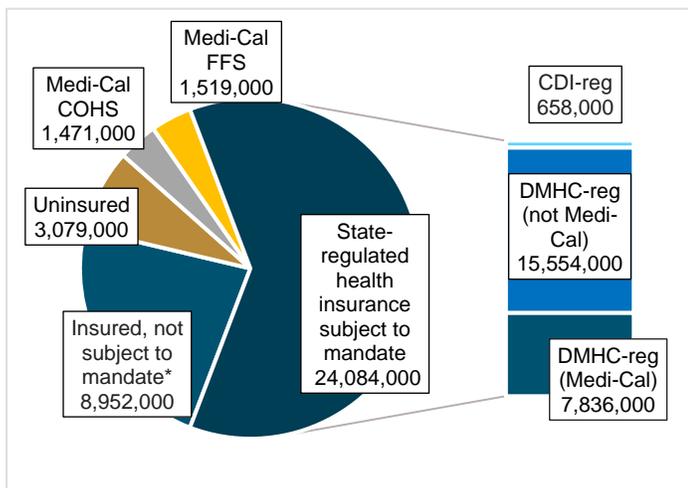
Maintaining the proper blood sugar (glucose) level is critical to maintaining good health and preventing complications for people with diabetes mellitus (DM). Continuous glucose monitors (CGMs) may be used by patients and healthcare providers to manage glucose levels. CGMs can be used retrospectively (a patient wears the CGM for 72 hours and the data is used by a provider to inform a patient's treatment plan) or in real-time (CGMs are worn continuously by patients over long periods of time and are able to see the glucose levels). CGMs can be used adjunctively with self-monitoring blood glucose (SMBG), therapeutically to make treatment decisions, or as a component of an artificial pancreas or an insulin infusion pump.

BILL SUMMARY

Through alteration of the Welfare and Institutions Code (WIC), AB 447 would require Medi-Cal coverage of "continuous glucose monitors, as medically necessary, for the maintenance and treatment of type 1 diabetes, type 2 diabetes, and gestational diabetes." Approximately 10.8 million Californians receive health insurance through Medi-Cal Managed Care plans, County Organized Health Systems (COHS), or the DHCS operated fee-for-service (FFS) program.

IMPACTS

Figure 1. Health Insurance in CA and AB 447



*Such as enrollees in Medicare or self-insured products
 Source: California Health Benefit Review Program, 2017

Benefit Coverage, Utilization, and Cost

Benefit Coverage

Currently, CHBRP estimates that 90.7% of beneficiaries with Medi-Cal Managed Care insurance coverage that would be subject to AB 447 have coverage for CGMs for the treatment and management of diabetes. Conversely, 0% of beneficiaries in the Medi-Cal fee-for-service program have coverage for CGMs for the treatment and management of diabetes. In comparison, all of the commercial DMHC-regulated and CDI-regulated health plans in California who responded to CHBRP’s survey reported covering the use of CGMs for treatment and management of diabetes. AB 447 would codify the requirement to cover CGMs for all Medi-Cal beneficiaries, resulting in an added benefit for 9.3% of Medi-Cal managed care beneficiaries (plus 100% of those in fee-for-service). In 2018, CHBRP estimates that the fee-for-service Medi-Cal program will represent 14% of Medi-Cal beneficiaries.

Utilization

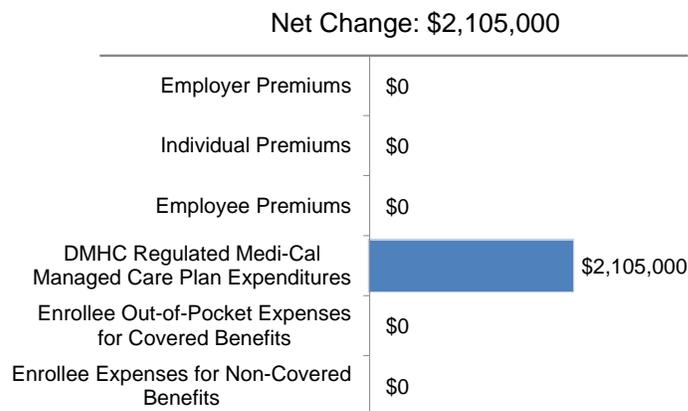
At baseline, 3.979 CGMs are estimated to be used per 1,000 beneficiaries in Medi-Cal, regardless of the type of coverage (Managed Care, COHS, or fee-for-service). Due to the addition of CGM coverage for 9.3% of beneficiaries in Medi-Cal managed care plans, the postmandate use of

CGMs is estimated to be 4.386 per 1,000 beneficiaries. This represents a 10.2% increase in CGM use by Medi-Cal managed care plan beneficiaries due to the mandate. CHBRP estimates that use of CGMs would increase to 4.386 per 1,000 enrollees in both COHS plans and the fee-for-service program.

Expenditures

AB 447 would increase total net annual expenditures by \$2,105,000 (0.0075% of managed care expenditures) for Medi-Cal managed care plans. Enrollees would not see an increase in out-of-pocket expenditures because of the prohibition on cost sharing for low-income beneficiaries in Medi-Cal. The state expenditures for Medi-Cal COHS Plans are estimated to increase by \$385,000 due to 9.3% of the COHS enrollees gaining coverage for CGMs due to AB 447. Postmandate use of CGMs in fee-for-service Medi-Cal results in an unknown increase in overall fee-for-service program expenditures.

Figure 2. Expenditure Impacts of AB 447, by Category, Postmandate



Source: California Health Benefit Review Program, 2017

CalPERS

AB 447 would not impact enrollees obtaining health insurance through CalPERS negotiated plans.

Number of Uninsured in California

There is no measurable impact projected.

Medical Effectiveness

Evidence of effectiveness of CGMs is strongest for real-time use by type 1 diabetes mellitus (T1DM) patients, which shows clear and convincing evidence of improved glycemic control (HbA1c) (with consistent CGM adherence). Overall, there is limited evidence that use of real-time CGMs for patients with T1DM are effective. A preponderance of evidence found the use of retrospective CGMs for patients with T1DM are not effective.

There is limited evidence that retrospective and real-time use of CGMs are not effective for patients with type 2 diabetes mellitus (T2DM).

Evidence is limited for retrospective CGM and insufficient for real-time CGM for improving glucose levels or maternal pregnancy or infant health outcomes for women with gestational diabetes mellitus (GDM).

Public Health

Patients most likely to benefit from use of CGMs include those over age 24 years (or selected children, teens, or young adults) who are insulin dependent and/or have hypoglycemic unawareness (ADA, 2017; Peters et al., 2016).¹ In the first year postmandate, CHBRP projects that the 2,255 additional CGM users, who use the CGM consistently, would see improvements in glycemic control as compared with self-monitoring blood glucose testing alone. This estimate is supported by a preponderance of evidence that CGMs are medically effective for those insulin-dependent patients and those who are hypoglycemia unaware, and who are able to maintain adequate adherence to CGM.

In the first year postmandate, CHBRP projects AB 447 would reduce statewide disparities in access to CGMs between low-income and middle-to-high income patients with diabetes by bringing Medi-Cal coverage of CGMs into parity with that of the privately insured population. Thus, AB 447 would improve the opportunity for better glycemic management among those low-income individuals who access and consistently use the newly covered CGMs. The use of CGMs is associated with improved blood sugar control, but there is no or limited evidence that CGM use directly led to improved clinical outcomes, reduced emergency room or inpatient use, or cost savings when compared to the current standard of care (i.e., self-

monitoring without CGMs) over 12 months or shorter periods of time.

Long-term Impacts

There is insufficient evidence around long-term CGM use and cost savings, and CHBRP does not anticipate differences over time that are different from the short-term estimates.

The impact of AB 447 on DM-related-comorbidities and premature mortality is unknown due to the lack of evidence regarding long-term health outcomes of CGM use. However, well-controlled blood glucose results in fewer DM-related comorbidities (blindness, amputations, kidney disease, etc.). Therefore, for those patients who attain good glycemic control through a CGM, these DM-related comorbidities that are known to lead to premature death could be prevented, delayed, or ameliorated.

Essential Health Benefits and the Affordable Care Act

AB 447 would not require coverage for a new state benefit mandate within the state-regulated private market and therefore will not exceed the definition of EHBs in California.

¹ Refer to CHBRP's full report for full citations and references.