

# UC Office of the President

## Report to California Legislature

### **Title**

Analysis of California Assembly Bill 447: Continuous Glucose Monitors

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# California Health Benefits Review Program

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## Analysis of California Assembly Bill 447 Continuous Glucose Monitors

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A Report to the 2017-2018 California State Legislature

April 12, 2017

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# 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

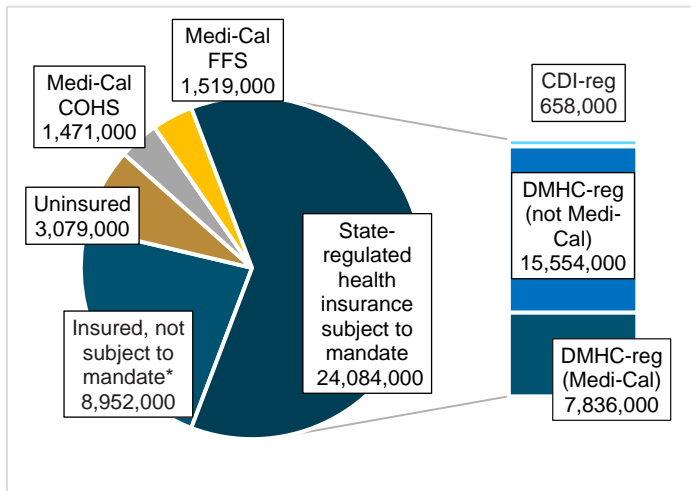
Maintaining the proper blood sugar (glucose) level is critical to maintaining good health and preventing complications for people with diabetes mellitus (DM). Continuous glucose monitors (CGMs) may be used by patients and healthcare providers to manage glucose levels. CGMs can be used retrospectively (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

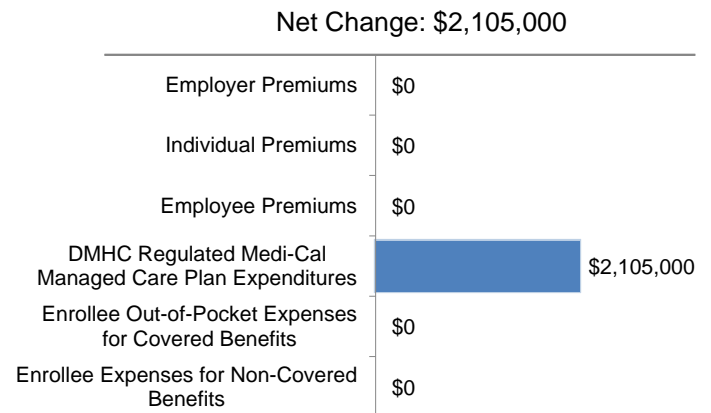
At baseline, 3.979 CGMs are estimated to be used per 1,000 beneficiaries in Medi-Cal, regardless of the type of coverage (Managed Care, COHS, or fee-for-service). Due to the addition of CGM coverage for 9.3% of beneficiaries in Medi-Cal managed care plans, the postmandate use of

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).<sup>1</sup> 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.

<sup>1</sup> Refer to CHBRP's full report for full citations and references.

A Report to the California State Legislature

Analysis of California Assembly Bill 447  
Continuous Glucose Monitors

April 12, 2017

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## ABOUT CHBRP

The California Health Benefits Review Program (CHBRP) was established in 2002. As per its authorizing statute, CHBRP provides the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit bills. The state funds CHBRP through an annual assessment on health plans and insurers in California.

An analytic staff in the University of California's Office of the President supports a task force of faculty and research staff from several campuses of the University of California to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact, and content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP reports and other publications are available at [www.chbrp.org](http://www.chbrp.org).

## TABLE OF CONTENTS

About CHBRP .....	v
List of Tables and Figures .....	vii
Policy Context .....	10
Bill-Specific Analysis of AB 447, Continuous Glucose Monitors .....	10
Background on Continuous Glucose Monitors and Diabetes Mellitus .....	14
Diabetes Mellitus Management: Measuring Blood Glucose .....	16
Medical Effectiveness .....	20
Study Findings .....	23
Summary of Findings .....	37
Benefit Coverage, Utilization, and Cost Impacts .....	41
Baseline and Postmandate Benefit Coverage .....	41
Baseline and Postmandate Utilization .....	42
Baseline and Postmandate Per-Unit Cost .....	42
Baseline and Postmandate Expenditures .....	42
Other Considerations for Policymakers .....	44
Public Health Impacts .....	50
Estimated Public Health Outcomes .....	50
Impact on Disparities in CGM Use and Glycemic Control .....	53
Estimated Impact on Financial Burden .....	54
Long-Term Impacts .....	55
Long-Term Utilization and Cost Impacts .....	55
Long-Term Public Health Impacts .....	55
Appendix A    Text of Bill Analyzed .....	A-1
Appendix B    Literature Review Methods .....	B-1
Appendix C    Cost Impact Analysis: Data Sources, Caveats, and Assumptions .....	C-1
Appendix D    Information Submitted by Outside Parties .....	D-1
References	
California Health Benefits Review Program Committees and Staff	
Acknowledgements	



## LIST OF TABLES AND FIGURES

<b>Table 1.</b> AB 447 Impacts on Benefit Coverage, Utilization, and Cost, 2018 .....	viii
<b>Table 2.</b> Prevalence of Type 1 and Type 2 Diabetes among Adults Diagnosed with Diabetes Mellitus who are Medi-Cal Beneficiaries, 2015 .....	16
<b>Table 3.</b> Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2018 .....	46
<b>Table 4.</b> Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2018 .....	48
<b>Table 5.</b> Diagnosis Codes Used in the Analysis of AB 447 to Determine Patients with Diabetes .....	C-2
<b>Table 6.</b> CPT and HCPC Codes Used in the Analysis of AB 447 to Classify Continuous Glucose Monitoring Devices and Other Diabetes Supplies .....	C-3
<b>Figure 1.</b> Number of Enrollees in Medi-Cal, 2018 .....	10
<b>Figure 2.</b> Diagram of CGM Process .....	17
<b>Figure 3.</b> Diagram of Relationship among CGM Components.....	17
<b>Figure 4.</b> Sample Comparison of Information Provided by SBGM and CGM .....	18
<b>Figure 5.</b> Retrospective Continuous Glucose Monitors for Type 1 Diabetes Mellitus.....	37
<b>Figure 6.</b> Real-Time Continuous Glucose Monitors for Type 1 Diabetes Mellitus .....	38
<b>Figure 7.</b> Retrospective Continuous Glucose Monitors for Type 2 Diabetes Mellitus.....	39
<b>Figure 8.</b> Real-Time Continuous Glucose Monitors for Type 2 Diabetes Mellitus .....	39
<b>Figure 9.</b> Retrospective Continuous Glucose Monitors for Gestational Diabetes Mellitus .....	40
<b>Figure 10.</b> Real-Time Continuous Glucose Monitors for Gestational Diabetes Mellitus.....	40

**Table 1.** AB 447 Impacts on Benefit Coverage, Utilization, and Cost, 2018

	Baseline	Postmandate	Increase/ Decrease	Percentage Change
<b>Benefit coverage</b>				
Total enrollees with health insurance subject to state-level benefit mandates (a)	24,048,000	24,048,000	0	0%
Total Medi-Cal Managed Care enrollees with health insurance subject to AB 447	7,836,000	7,836,000	0	0%
Number of Medi-Cal Managed Care enrollees with health insurance fully compliant with AB 447	7,110,000	7,836,000	726,000	10.2%
Percentage of Medi-Cal Managed Care enrollees with health insurance fully compliant with AB 447	90.7%	100.0%	9%	10.2%
<b>For Medi-Cal Managed Care Population Only</b>				
Number of Medi-Cal Managed Care Enrollees Diagnosed with				
Type 1 Diabetes	63,695	63,695	0	0%
Type 2 Diabetes	547,782	547,782	0	0%
Gestational Diabetes	24,979	24,979	0	0%
Percentage of Medi-Cal Managed Care Enrollees Diagnosed with				
Type 1 Diabetes	0.8%	0.8%	0%	0%
Type 2 Diabetes	7.0%	7.0%	0%	0%
Gestational Diabetes	0.3%	0.3%	0%	0%
<b>Utilization and unit cost</b>				
Number of Medi-Cal Managed Care enrollees using Continuous Glucose Monitors				
Type 1 Diabetes	18,428	20,476	2,048	11.1%
Type 2 Diabetes	1,829	2,032	203	11.1%
Gestational Diabetes	32	36	4	11.1%
Utilization (Units per 1,000 Covered Medi-Cal Managed Care Enrollees)				
Continuous Glucose Monitors	3.979	4.386	0.406	10.2%
Other Diabetes Supplies for Medi-Cal Managed Care enrollees using Continuous Glucose Monitors	7.646	8.427	0.781	10.2%
Average Annual Cost per User				
Continuous Glucose Monitors	\$883	\$883	\$0	0.0%
Other Diabetes Supplies for Medi-Cal Managed Care enrollees using Continuous Glucose Monitors	\$955	\$955	\$0	0.0%
Average per Medi-Cal Managed Care member per month expenditures				
Continuous Glucose Monitors	\$0.0927	\$0.1022	\$0.0095	10.2%

Other Diabetes Supplies for Medi-Cal Managed Care enrollees using Continuous Glucose Monitors	\$0.1002	\$0.1104	\$0.0102	10.2%
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**Expenditures**

Premium expenditures by payer

Private employers for group insurance	\$64,820,615,000	\$64,820,615,000	\$0	0.0000%
CalPERS HMO employer expenditures <sup>(b)</sup>	\$4,884,262,000	\$4,884,262,000	\$0	0.0000%
Medi-Cal Managed Care Plan expenditures <sup>(e)</sup>	\$27,983,856,000	\$27,985,961,000	\$2,105,000	0.0075%
Enrollees for individually purchased insurance	\$14,608,214,000	\$14,608,214,000	\$0	0.0000%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care <sup>(c)</sup>	\$20,387,090,000	\$20,387,090,000	\$0	0.0000%
<u>Enrollee expenses</u>				
Enrollee out-of-pocket expenses for covered benefits (deductibles, copayments, etc.)	\$13,565,623,000	\$13,565,623,000	\$0	0.0000%
Enrollee expenses for noncovered benefits <sup>(c)</sup>	\$0	\$0	\$0	0.00%
<b>Total expenditures</b>	<b>\$146,249,660,000</b>	<b>\$146,251,765,000</b>	<b>\$2,105,000</b>	<b>0.0014%</b>

Source: California Health Benefits Review Program, 2017.

Notes: (a) This population includes persons with privately funded (including Covered California) and publicly funded (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans) health insurance products regulated by DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employer-sponsored health insurance.

(b) As of June 1, 2016, 58.82% of CalPERS members were state retirees, state employees, or their dependents. CHBRP assumes the same ratio for 2018. It should be noted, however, that should CalPERS choose to make similar adjustments for consistency to the benefit coverage of enrollees associated with CalPERS' self-insured products, the fiscal impact on CalPERS could be greater.

(c) Enrollee premium expenditures include contributions to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal Managed Care.

(d) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. In addition, this only includes those expenses that will be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

(e) Does not include enrollees in COHS and Medi-Cal FFS. Assuming baseline prevalence of continuous glucose monitor users and utilization of other diabetes supplies were similar to Medi-Cal Managed Care, the state expenditures for Medi-Cal County Organized Health System Plans are estimated to increase by \$385,000. It seems likely there would also be an additional increase for the 1.5 million beneficiaries receiving health coverage through the Medi-Cal FFS program, although the exact amount is unknown.

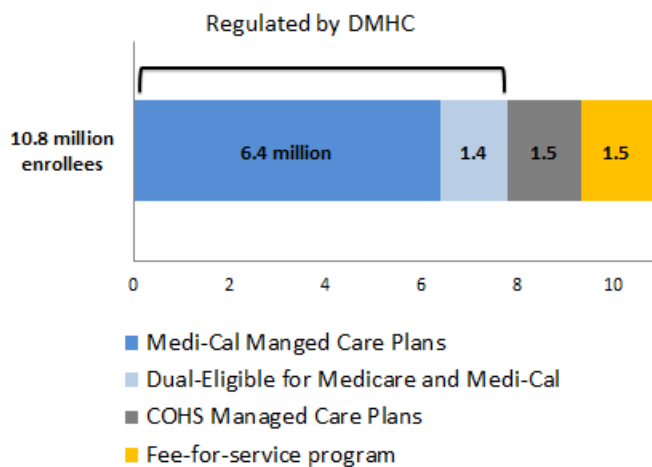
Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS= County Organized Health System; DMHC = Department of Managed Health Care.

## POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)<sup>2</sup> conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 447, Continuous Glucose Monitors (CGMs).

Approximately 10.8 million Californians will receive full-scope health insurance through Medi-Cal Managed Care Plans, County Organized Health System (COHS) Managed Care Plans, and the fee-for-service (FFS) program in 2018 (28% of all Californians) (Figure 1). The 7.8 million beneficiaries enrolled in Medi-Cal Managed Care plans have health insurance regulated by the Department of Managed Health Care (DMHC), while beneficiaries receiving health insurance through COHS plans and the FFS program have plans overseen by the Department of Health Care Services (DHCS). Table 1 only includes information regarding DMHC-regulated plans. If enacted, AB 447 would affect the health insurance of beneficiaries in DMHC-regulated Medi-Cal Managed Care plans, DHCS-operated Medi-Cal FFS program, and Medi-Cal COHS Managed Care Plans. AB 447 does not impact privately funded Department of Managed Health Care (DMHC) or California Department of Insurance (CDI) regulated plans or policies.

**Figure 1.** Number of Enrollees in Medi-Cal, 2018



Source: California Health Benefits Review Program, 2017

### Bill-Specific Analysis of AB 447, Continuous Glucose Monitors

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.”

The full text of AB 447 can be found in Appendix A

<sup>2</sup> CHBRP’s authorizing statute is available at <http://chbrp.org/faqs.php>.

## Analytic Approach and Key Assumptions

The bill language does not specify which types of CGMs would be subject to the coverage requirement, should the bill be enacted. For the purposes of this analysis, CHBRP assumes that all FDA-approved CGMs would be included in this coverage requirement.

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 for real-time use (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. CHBRP assumes all three components of CGMs would be covered (the sensor, the transmitter, and the receiver/display). See the *Background on Continuous Glucose Monitors and Diabetes* section for more details.

In the Benefit Coverage, Utilization, and Cost Impacts analysis, CHBRP grouped all CGMs and its components together due to current standards of coding and billing. Given the use of commercial claims data obtained through MarketScan to estimate changes in utilization and expenditures, there is no way to differentiate between real-time and retrospective use to manage diabetes. Additional details are included in the Benefit Coverage, Utilization, and Cost Impacts section.

CHBRP estimates that 90.7% of beneficiaries with Medi-Cal Managed Care insurance coverage currently 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 CGM 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 CGM for treatment and management of diabetes.

The Welfare and Institutions (WIC) Code<sup>3</sup> states a service is 'medically necessary' or a 'medical necessity' when it is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain." AB 447 does not alter this definition and does not expand upon how medical necessity would be applied to use of CGMs. CHBRP assumes the bill would not prohibit generally applicable utilization management techniques, including health plan application of medical necessity criteria and prior authorization requirements. Details about how professional associations define medical necessity are included in the Background section below.

## General Caveat for All CHBRP Analyses

It is important to note that CHBRP's analysis of proposal benefit mandate bills address the incremental effects — how the proposed legislation would impact benefit coverage, utilization, costs, and public health compared to current coverage. CHBRP's estimates of these incremental effects are presented in this report.

## Interaction with Existing Requirements

AB 447 may interact and align with the following state and federal mandates or provisions.

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<sup>3</sup> Welfare and Institutions Code (14059.5)

## State Requirements

### *California law and regulations*

California law requires DMHC-regulated plans<sup>4</sup> to cover diabetes education, management, and treatment. However, it is unclear whether CGMs are included in this requirement.<sup>5</sup>

Existing WIC requires Medi-Cal coverage of durable medical equipment and medical supplies, subject to utilization controls.<sup>6</sup> However, CGMs are not explicitly included in this code. Similarly, although existing WIC<sup>7</sup> requires Medi-Cal coverage of diabetic test supplies when provided by a pharmacy, this does not encompass coverage of CGMs.

### California Children's Services (CCS)

CGMs are required to be covered for children receiving coverage through California Children's Services (CCS).<sup>8</sup> As of 2017, the CCS program is operated as a fee-for-service carve-out in most counties in California, meaning that children receiving Medi-Cal through the managed care plans or COHS receive additional coverage for qualifying diseases or conditions through a fee-for-service financing component that is separate from their general Medi-Cal coverage. Currently, five COHS counties are "carved-in" CCS counties: Napa, San Mateo, Santa Barbara, Solano, and Yolo. Diabetes is a CCS-qualifying disease, but management of diabetes may be done via the CCS carve-out (delivered through CCS special care centers or children's hospital providers) or through a child's assigned managed care plan or COHS coverage via a non-CCS provider.

The number of children and adults with CCS-only coverage who will obtain all diabetes care through the fee-for-service Medi-Cal system because they have no additional Medi-Cal managed care coverage is relatively small. In 2012, there were approximately 190,500 children receiving benefits through CCS, and 4% were diagnosed with diabetes mellitus.<sup>9</sup> Some of these children with diabetes mellitus could have received a CGM, either through the CCS carve out or through the Medi-Cal managed care plan or COHS. In either case, the CGM is a currently covered benefit. This small number of children (less than 1%) who would have had coverage in both the CCS program and their managed care or COHS plans is unlikely to have a meaningful effect on the utilization or expenditure estimates in this report. If the current level of use of CGM in the FFS carve-out is relatively high, CHBRP would be overestimating the spending on CGM due to new coverage. Given the overlap in coverage for CCS patients who obtain services partially through the FFS program and their COHS or managed care plan, it is likely that most of these enrollees are captured in the COHS and managed care plans due to their full-scope Medi-Cal coverage; CHBRP does not think an overestimate of new coverage is likely. DHCS is currently transitioning the CCS population to a "whole child model" via SB 586<sup>10</sup>, which would move at least 25,000 CCS enrollees into COHS "carved-in" programs during 2017. The remainder may transition from 2018 to 2021.

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<sup>4</sup> California Health & Safety Code (1367.51)

<sup>5</sup> As of publication of this report, CHBRP has not received a response from DMHC or DHCS regarding coverage of CGMs and the interaction with existing laws.

<sup>6</sup> Welfare and Institutions Code [14132 (m)]

<sup>7</sup> Welfare and Institutions Code [14132 (ac)]

<sup>8</sup> Department of Health Care Services. Number Letter 03-0317: Continuous Glucose Monitoring (CGM) as a CCS/CHPP Program Benefit. 2017. Available at <http://www.dhcs.ca.gov/services/ccs/Documents/ccsnl030317.pdf>. Accessed on April 3, 2017.

<sup>9</sup> Department of Health Care Services. California Children's Services, Dataset. Available at <http://www.dhcs.ca.gov/services/ccs/Pages/Dataset.aspx>. Accessed April 4, 2017.

<sup>10</sup> California Health & Safety Code (123835, 123850) and Welfare and Institutions Code (14093.06, 14094.2, 14094.3, 14094.4)

It is unclear whether CGMs are currently covered for children under age 21 enrolled in Medi-Cal through the Early Periodic Screening, Diagnostic, and Treatment (EPSDT) Program. CHBRP assumes that CGMs are covered for children according to the Medi-Cal Managed Care Plan's benefits.

### *Similar requirements in other states*

CHBRP is aware of at least one state Medicaid program that currently provides coverage for CGMs. Indiana Health Coverage Programs reimburses for use of retrospective and real-time CGMs for adults and children (aged 7 and above) when the service is considered medically necessary, although the Provider Reference Model does not indicate whether CGMs are covered for T1DM, T2DM, or GDM (Indiana Health Coverage Programs, 2016).

## **Federal Requirements**

### *Medicare*

In January 2017, the Centers for Medicare & Medicaid Services (CMS) ruled therapeutic CGMs would be covered under the Durable Medical Equipment (DME) Medicare Part B benefit when “determined to be reasonable and necessary for the treatment of diabetes illness.”<sup>11</sup> Replacement of essential accessories for the monitor would also be covered. For Medi-Cal beneficiaries dually enrolled in Medicare (dual-eligibles), Medicare is the primary payer. CHBRP assumes that cost sharing for Medicare beneficiaries using therapeutic CGMs would be covered by Medi-Cal and that Medicare beneficiaries do not have coverage for adjunctive CGMs. However, CHBRP also assumes that Medi-Cal reimbursements for CGMs are below Medicare's reimbursement, meaning Medi-Cal would not pay for a dual-eligible's cost sharing portion. Medi-Cal would be the primary payer if a dually eligible Medi-Cal/Medicare beneficiary receives a medically necessary adjunctive CGM.

### *Affordable Care Act*

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how AB 447 may interact with requirements of the ACA as presently exists in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).<sup>12</sup>

Any changes at the federal level may impact the analysis or implementation of this bill, were it to pass into law. However, CHBRP analyzes bills in the current environment given current law.

CHBRP is unaware of additional federal laws or regulations that would interact with the provisions of AB 447.

### **Essential Health Benefits**

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

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<sup>11</sup> Ruling No [CMS-1682-R] (January 12, 2017)

<sup>12</sup> The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to QHPs sold in Covered California — to cover 10 specified categories of EHBs. Resources on EHBs and other ACA impacts are available on the CHBRP website: [http://www.chbrp.org/other\\_publications/index.php](http://www.chbrp.org/other_publications/index.php).



## BACKGROUND ON CONTINUOUS GLUCOSE MONITORS AND DIABETES MELLITUS

Maintaining the proper blood sugar (glucose) level is critical to maintaining good health and preventing complications for people with diabetes mellitus (DM). This section defines DM, the prevalence of DM, and describes the subject of AB 447, the continuous glucose monitor (CGM), which may be used by patients and healthcare providers to manage glucose levels.

### What Is Diabetes Mellitus?

Diabetes mellitus (DM) is a chronic disease with short- and long-term health effects (discussed below) that prevent the proper production of and/or response to insulin, a hormone that facilitates the transfer of glucose into cells to provide energy (NIDDKD, 2017a). There are three primary types of diabetes (and all are included in AB 447):

- **Type 1 diabetes mellitus (T1DM)** is an autoimmune disease, most commonly diagnosed during childhood/adolescence that attacks and destroys the insulin-producing cells in the pancreas. In addition to dietary modifications, treatment requires lifetime use of daily insulin injections and/or an insulin pump used to replace the patient's impaired ability to produce insulin, and attention to diet.
- **Type 2 diabetes mellitus (T2DM)** is most commonly diagnosed in middle-aged or older adults, although it has been increasingly diagnosed in children and adolescents (CDC, 2015). Type 2 diabetes prevents the body from properly responding to insulin (known as insulin resistance). In some cases, people with T2DM also do not make enough insulin. It is associated with obesity, genetics, and lifestyle patterns. Treatments for T2DM include diet modifications, exercise, weight loss, oral medications, non-insulin injected medications, and/or insulin depending on the severity of the disease, which progresses over time especially with inadequate treatment.
- **Gestational diabetes (GDM)** develops only in women who are pregnant and is generally diagnosed in the second trimester (Blumer et al., 2013). For most, this is a transient condition that resolves following delivery; however, these women remain at higher risk for T2DM later in life. Treatments include diet modifications, exercise, oral medication, and insulin.

### Diabetes Mellitus: Short- and Long-Term Effects

#### *Short-term effects*

Achieving stable, healthy blood glucose levels is challenging for individuals with diabetes. On a daily basis, people with diabetes can experience swings between very high blood glucose levels (*hyperglycemia*) and extremely low blood glucose levels (*hypoglycemia*). Changes in stress, sleep, physical activity, diet, and acute illnesses contribute to hyper- and hypoglycemic events. *Hyperglycemia* is exhibited through increased thirst or hunger, frequent urination, headache, and fatigue. Left untreated, particularly in T1DM, it may develop into ketoacidosis where the body develops a toxic amount of ketones (toxic acids) for energy, which can lead to coma or death.

Symptoms of *hypoglycemia* can begin as mild (e.g., anxiety, sleepiness, and tremors) and, if left untreated, escalate to serious health events such as cognitive dysfunction, seizures, coma, and death (Unger, 2012). Some patients (between 20% and 40% of T1DM patients and 10% of T2DM patients) are



diagnosed with *hypoglycemia unawareness*, a condition in which individuals are unable to sense dangerously low blood sugar early enough to reverse it, which puts them at high risk for severe hypoglycemic events requiring hospitalization (Martin-Timon and Canizo-Gomez, 2015). People with this condition are required to perform more frequent blood glucose testing than those who can feel their blood glucose levels dropping. Vigersky (2015) estimated that among people with hypoglycemic unawareness, 2.4 to 8.1 hospitalizations occur annually among T1DM patients, and 2.1 to 5.9 hospitalizations per year among T2DM patients. Hypoglycemia unawareness occurs more frequently among those with a longer duration of diabetes, who are insulin dependent, and/or have a history of hypoglycemic events (Martin-Timon and Canizo-Gomez, 2015).

For pregnant women, uncontrolled GDM may lead to complications during pregnancy including abnormal fetal growth, need for extra testing during pregnancy, preeclampsia, and possible early and/or more invasive delivery methods including cesarean section. Infants of women with GDM can suffer complications during and directly after birth, including hypoglycemia and hyperbilirubinemia (jaundice), but most are transient with some infants requiring NICU care (NIDDKD, 2017b).

### *Long-term effects*

Time spent in hyperglycemia and frequency and severity of hyper- and hypoglycemia over a lifetime are associated with serious morbidity and mortality outcomes. In the United States, DM is the leading cause of blindness, amputations, and kidney failure, and a key contributor to stroke, heart disease, dental disease, nerve damage, and premature death (CDPH, 2012) due to suboptimal blood sugar control. In the long term, uncontrolled GDM puts pregnant women and their infants at higher risk of developing T2DM later in life (NIDDKD, 2017b). Although people with diabetes may not avoid all associated comorbidities, tightly controlled blood glucose over time may prevent, delay, or ameliorate some comorbidities.

## **Prevalence of Diabetes Mellitus in the Medi-Cal Population**

Diabetes is one of the most common chronic conditions in California and the United States. According to the 2015 California Health Interview Survey (CHIS), about 11% of the adult Medi-Cal population has been diagnosed with diabetes, as compared with about 6% of the privately insured, adult California population (CHIS, 2017a).

AB 447 would affect only the Medi-Cal population. The following are the most recent prevalence estimates by type of diabetes for adults, pregnant women, and youth in Medi-Cal:

- *Adults:* Of the estimated 11% (742,000) of adult Medi-Cal beneficiaries with diabetes (aged 18-64 years), about 13% have T1DM and about 80% have T2DM in 2015 (CHIS, 2017c). (Table 2)
- *Pregnant women:* The 2015 CHIS estimates that almost 8% of pregnancies among non-diabetic, Medi-Cal beneficiaries experience gestational diabetes (CHIS, 2017d), which is similar to national estimates that range between 6% to 20% of pregnancies complicated by gestational diabetes (depending on diagnostic criteria used) (ACOG, 2013; Vandorsten et al., 2013).
- *Youth:* CHIS does not report diabetes in those under age 18 years after 2007. The most recent prevalence data CHBRP found are national 2012 data from the CDC, which estimates that 0.25 percent of youth under age 20 years are diagnosed with T1DM (~80%) and T2DM (~20%) (CDC, 2014a; ADA, 2017).

**Table 2.** Prevalence of Type 1 and Type 2 Diabetes among Adults Diagnosed with Diabetes Mellitus who are Medi-Cal Beneficiaries, 2015

Diabetes type	Percent of Medi-Cal beneficiaries diagnosed with diabetes	Medi-Cal beneficiaries diagnosed with diabetes
<b>Medi-Cal Beneficiaries Aged 18-64 Years with Diabetes</b> (n=742,000 or 11% of Medi-Cal 18-64 yrs in 2015)		
Type 1	13.4%	100,000
Type 2	80.8%	599,000
Unknown/another type*	5.8%	43,000
<b>Medi-Cal Beneficiaries Aged 65+ Years with Diabetes</b> (n=381,000 or 31% of Medi-Cal 65+ yrs in 2015)		
Type 1*	8.1%	31,000
Type 2*	89.4%	341,000
Unknown/another type*	2.5%	9,000

Source: California Health Benefits Review Program, 2017. Based on 2015 data from the California Health Interview Survey (CHIS).

\*CHIS reports these data as statistically unstable. Note: CHIS permits respondents to select “Unknown or Another type” in response to its “type of diabetes” question. Examples of other types of diabetes may include maturity-onset diabetes of youth; from surgery, medications, infections, pancreatic disease, or other illnesses including cystic fibrosis.

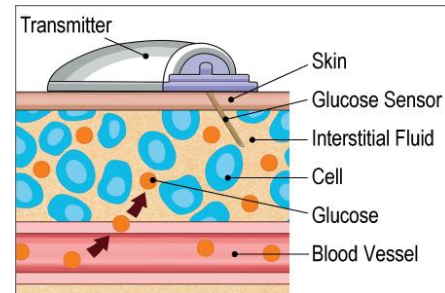
## Diabetes Mellitus Management: Measuring Blood Glucose

Managing diabetes requires checking blood glucose levels through lab tests (HbA1c periodically ordered by health care providers) and daily patient self-monitoring blood glucose (SMBG), also known as a finger stick. HbA1c indicates a patient’s average glucose level over the last 3 months. The lab results are used by health care providers to inform the patient’s diabetes management plan (NIDDKD, 2017a). Patients perform SMBG tests 1 to 10 times/day to obtain “snapshot” glucose readings to help them adjust their insulin, diet, physical activity, or oral medication throughout the day and night. More frequent testing is required for insulin-dependent patients and those who have uncontrolled blood sugars, including hypoglycemia and hyperglycemia. SMBG requires the patient to prick the skin (commonly the finger for the most accurate reading) for a drop of blood, which is applied to a test strip. The strip is inserted into a handheld blood glucose monitor (glucometer) which displays a reading for the current glucose level. Optimal HbA1c is at 7 percent which corresponds to an average SMBG number of 154mg/dL (UpToDate, 2017). Blood sugars are best kept between 80 and 160 mg/dL throughout the day (McCulloch et al., 2017).

## Continuous Glucose Monitors

In addition to HbA1c lab tests and self-monitoring blood glucose (SMBG), patients and providers may also use continuous glucose monitors (CGM) to help manage diabetes. Three manufacturers produce FDA-approved CGMs in the U.S. (i.e., Abbott, Dexcom, and Medtronic). These waterproof monitors, also called continuous interstitial glucose monitors, use a thin plastic catheter inserted into the subcutaneous skin (fat layer) just under the skin of the arm, back, or trunk to measure the amount of glucose in the fluid around the cells, called interstitial fluid (Figure 2) (Castle and Jacobs, 2016).

**Figure 2.** Diagram of CGM Process

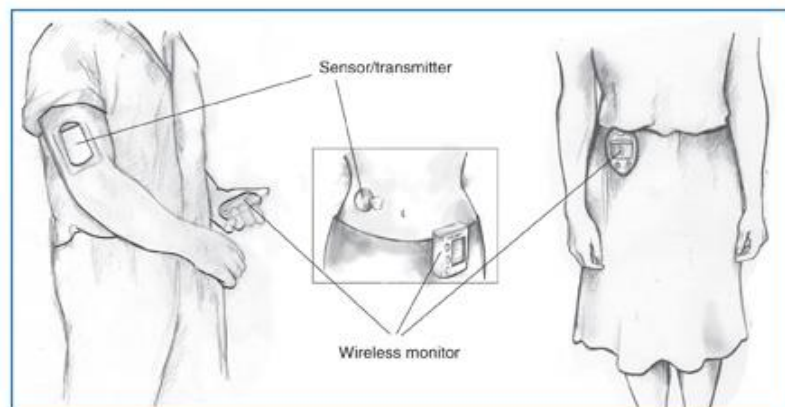


Source: Naomi Berrie Diabetes Center, Columbia University Medical Center, 2014

CGMs have three components:

- A *sensor* with a plastic catheter (inserted with a needle) that is attached to the skin with adhesive tape; or integrated with an insulin pump, depending on the model.
- a *transmitter* that attaches to the sensor; and
- an optional *receiver/display* that can be worn on a belt or in a pocket (or can be a part of an insulin pump) for patients using a CGM in real time (Figure 3).

**Figure 3.** Diagram of Relationship among CGM Components



Source: NIDDKD, 2017c.

Sensors are replaced within 7 days, and transmitters must be recharged every 3 to 14 days. Many CGMs have software that enables patient use of smart devices or remote monitoring (Robard, 2016).

## Retrospective or Real-time Use of CGMs

CGMs may also be categorized as *retrospective* or in *real time* based on how often and by whom the glucose level readings are reviewed. Under the retrospective (professional) scenario, a health care provider asks the patient to wear the CGM for 72 hours (to one week) to record glucose measurements every 5 to 15 minutes for the duration. The patient does not see the CGM glucose levels while wearing the device. The patient returns to the provider who downloads and analyzes the retrospective data for patterns in glucose control. The provider can use this retrospective data to see when hyper- and hypoglycemia events undetected by SMBG are occurring, and to understand why a patient's HbA1c remains uncontrolled even if SMBG results appear controlled. This detailed information can be used to inform the patient's treatment regimen including changes to insulin, other medications, and diet that are meant to improve diabetes control and subsequent long-term diabetes outcomes.

Under the *real-time* use scenario, CGMs are worn by the patient to actively and consistently monitor glucose throughout the day and night. The patients are able to see the CGM glucose levels on their receivers (or smart phones) as the measurements are taken throughout the day and night. They also

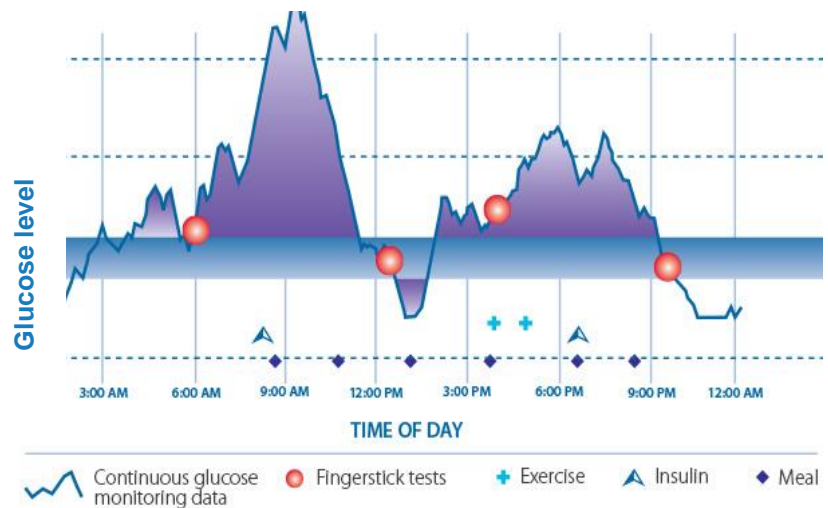
have the option to set an alarm to alert them when glucose levels go too high or too low (NIDDK, 2017c). For real-time use, patients must move the sensor to a different place on the body at least once per week (McCulloch et al., 2017). As with data collected from a retrospective CGM, the patient and the provider can also review the detailed data to better understand the user’s glucose level patterns over time and adjust the treatment regimen accordingly.

### Differences Between SMBG and CGM Glucose Readings

Most CGMs require users to calibrate the sensor with an SMBG test four times per day (McCulloch et al., 2017), and one FDA-approved CGM requires two tests per day. Most manufacturers of CGMs recommend that a CGM reading be calibrated against an SMBG test result before titrating insulin. *CGMs therefore do not entirely replace SMBG, but may decrease the number of daily SMBG tests, and provide additional information on glucose levels between SMBG readings.*

Figure 4 compares the different types of glucose level data provided by a CGM and SMBG test. The CGM provides numerous glucose readings daily (every 5-15 minutes), providing more data than the “snapshots” of SMBG readings (McCulloch et al., 2017). For patients using CGMs in real time, the data enable patients to react quickly to changes in glucose levels (e.g., asymptomatic hypoglycemia). It also provides a long-term, detailed data set that shows patterns in daily glucose levels over time to inform a sound diabetes management plan. For example, nocturnal hypoglycemia is not uncommon in T1DM. Using the warning alarm on the CGM or using retrospective data to predict when hypoglycemic events tend to occur during the night can help users learn when they should wake to administer sugar, or guide changes in diet or reduction in insulin doses. Retrospective use of CGMs provide similar detailed data to providers that shows a pattern of glucose levels over time, for a shorter duration (typically 72 hours) than real-time CGMs.

**Figure 4.** Sample Comparison of Information Provided by SBGM and CGM



Source: California Health Benefits Review Program, 2017. Based on graphic from Medtronic, 2015.

### Professional and Clinical Guidelines for Use of CGMs

AB 447 specifies coverage of CGMs as medically necessary; however, the bill does not define this term. Medical necessity determinations vary by health plan and are based upon practice guidelines and internal carrier policies. The following guidelines offer some indicators of how medical necessity may be defined, in part or in whole, by different plans and policies.

#### The American Academy of Clinical Endocrinologists

The American Association of Clinical Endocrinologists and the American College of Endocrinology (AACE/ACE) recommends CGM be considered for patients with T1DM and T2DM on a long-acting insulin

usually taken once daily (basal) with short-acting insulin taken at meal times (bolus) insulin therapy to improve HbA1c and reduce hypoglycemia (Hendelsman, 2015). AACE also finds that early reports suggest patients not taking insulin may benefit from CGMs, but this use has not been officially recommended.

### **American Diabetes Association**

The American Diabetes Association (ADA, 2017) states that CGMs can be used as a tool to help lower HbA1c in sub-groups of patients with T1DM and selected patients with T2DM. Specifically, the ADA recommends use of CGMs in conjunction with intensive insulin regimens for selected adults aged 25 and above with T1DM. CGMs may be helpful for children, teens, and younger adults, and for those with hypoglycemia unawareness and/or frequent hypoglycemic episodes, emphasizing that success is correlated with ongoing CGM adherence. Recognizing that variable adherence is an issue with CGMs, the ADA recommends that providers assess individual readiness for CGMs, and that they provide robust diabetes education, training, and support to support optimal CGM implementation and ongoing use.

### **The Endocrine Society**

The Endocrine Society's 2016 recommendations (Peters et al., 2016) include real-time CGM use for adult patients with T1DM who have HbA1c levels above target and who are willing and able to use CGMs on a near daily basis; and retrospective, intermittent CGM use in adult patients with T2DM who have HbA1c levels above 7% and are willing and able to use the device. All adults who use CGMs should receive education, training, and ongoing support to help achieve and maintain individualized glycemic goals.

### **Health Disparities in Diabetes Mellitus**

"Health disparity" denotes differences, whether unjust or not. "Health inequity" on the other hand, denotes differences in health [status or] outcomes that are systematic, avoidable, and unjust." (Wyatt et al., 2016). The literature denotes differences and disparities in diabetes prevalence, glucose testing, glycemic control and CGM utilization by race and income. See the *Public Health Impacts* section for details about these differences and disparities.

### **Societal Burden of Diabetes in California**

Based on data from 2008 and 2013, the Centers for Disease Control and Prevention (CDC) estimates that diabetes costs Medi-Cal \$3 billion annually in medical costs. For all payers across California, including Medi-Cal, the CDC estimates indirect costs for all patients with diabetes (e.g., absenteeism, presenteeism, household productivity loss, inability to work, and premature mortality) are \$30 billion annually (2013 dollars) and direct medical costs are \$20.4 billion (2013 dollars) (CDC, 2016).



## MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, AB 447 requires all DMHC-regulated Medi-Cal managed care plans, Medi-Cal County Organized Health Systems (COHS) plans, and the traditional fee-for-service (FFS) Medi-Cal program to cover continuous glucose monitors (CGM), as medically necessary, for the management and treatment of type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM), and gestational diabetes mellitus (GDM). This section summarizes the medical effectiveness review of the literature on the health outcomes and harms associated with the use of CGMs for the management of T1DM, T2DM, and GDM compared to self-monitoring of blood glucose (SMBG).

### Research Approach and Methods

Studies of the use of CGM for T1DM, T2DM, and GDM were identified through searches of PubMed, the Cochrane Library, and Web of Science, as well as websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network.

The medical effectiveness review searched the literature from 2000 to present. Due to the existence of two high-quality systematic reviews (with meta-analyses) conducted by Cochrane (Langendam et al., 2012) and the Agency on Healthcare Research and Quality (AHRQ) (Golden et al., 2012) in 2012 on the use of CGMs compared with SMBG in patients with T1DM, the medical effectiveness search related to T1DM was limited to studies published from 2012 to the present. The AHRQ systematic review also reviewed literature on the use of real-time CGMs compared with SMBG in patients with T2DM; thus, the medical effectiveness search related to real-time CGM and T2DM was limited to studies published from 2012 to present. To CHBRP's knowledge, no systematic reviews have been conducted on GDM, thus the medical effectiveness search related to GDM was broadened from 2000 to 2017.

Of the 967 unique articles identified in the literature review, 204 were reviewed for potential inclusion in this report on AB 447, and a total of 23 studies were included in the medical effectiveness review for this report. Only articles that directly addressed one of the four key questions (see below) were included. The other articles were eliminated because they did not focus on a relevant population, were of poor quality, did not report findings from clinical research studies, or were an excluded study design (e.g., conference abstracts); a more detailed discussion of exclusion reasons specific to this bill analysis are discussed below. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B

### Key Questions

1. What is the effectiveness of CGM on short- and long-term diabetes-related health outcomes compared to SMBG for patients with T1DM, T2DM, or GDM? Does the effectiveness differ by the type of CGM (retrospective versus real-time)?
2. What are the harms associated with the use of CGMs?

## Methodological Considerations

For this analysis, the medical effectiveness review excluded studies whose primary objective was to assess the impacts of counseling or behavioral interventions (for diet, physical activity) while using CGMs rather than the CGMs themselves. CHBRP also excluded studies if CGM use was one component of a larger intervention (e.g., nutrition counseling plus CGM). These studies have been conducted in patients with T2DM who are trying to control their diabetes with diet and exercise to determine whether the use of CGMs can support this effort. CHBRP also excluded the use of CGMs in an acute or inpatient setting, as this is a tightly medically regulated environment and is not a good representation of typical ambulatory use of CGM. Studies of pregnant women with pre-existing T1DM or T2DM were excluded, with the assumption that any benefits of CGM seen among those with T1DM, T2DM, or GDM would translate to this specific subpopulation. Studies that did not specify diabetes type were also excluded, as the cause and treatments vary by diabetes type and therefore CHBRP assumes CGM use and related outcomes could also vary by diabetes type and should be assessed separately. CHBRP also excluded head-to-head comparisons of different models of CGMs without a comparator group (such as SMBG or a blinded CGM group) as these studies aimed to distinguish between CGMs and not to determine the effectiveness of CGM as a monitoring approach. The review prioritized studies that compared CGM with a control group — most often SMBG, but some studies used a comparison group that wore a “blinded” real-time monitor (the monitor did not display glucose readings and the data was only available for download and review). If comparative studies were not available, CHBRP included uncontrolled studies.

As mentioned above, CHBRP based its review of T1DM on two well-conducted systematic reviews, both of which meta-analyzed some outcomes. The Cochrane review included 22 unique randomized controlled trials (RCTs) of patients with T1DM using either retrospective CGM (7 unique RCTs; 5 in children, 2 in adults) or real-time CGM (15 unique RCTs; 1 trial included only children, 6 included only adults, 3 trials included both children and adults [but presented stratified results by age], and 5 included a broad range of patient ages [but did not stratify results by age]). As mentioned, the Cochrane review included trials of patients across a broad age range and the mean age of patients enrolled in these trials ranged from 23 to 33 years; therefore, we discuss the results of these trials along with the results presented for adults. All of the included trials were industry sponsored; the CGM manufacturer provided the grant funding or the CGM device. Per the Cochrane review, 10 trials reported using a statement of independency or different types of CGM systems and Cochrane considered that those actions prevented inappropriate influence. The AHRQ systematic review included nine unique RCTs of patients with T1DM using real-time CGM. All of these trials were included in the broader Cochrane review. However, the AHRQ systematic review performed relevant meta-analyses of some outcomes that were not included in the Cochrane review. The medical effectiveness review will report results from the AHRQ meta-analysis where relevant.

As discussed in the *Background on Continuous Glucose Monitors and Diabetes Mellitus* section, CGMs are used in addition to SMBG, and the purpose of CGMs is to improve glucose control over control achieved with the use of SMBG alone. As mentioned above, the medical effectiveness review only included studies comparing patients using SMBG alone versus patients using CGMs *in addition to SMBG*. In order to conclude that CGMs are effective, a study needed to show significant improvements in measures of glucose control (HbA1c, hypoglycemia, hyperglycemia, etc.) through the use of CGMs as compared to SMBG alone.

## Outcomes Assessed

To address key question #1, CHBRP included studies reporting relevant short- and long-term health outcomes associated with diabetes mellitus. Relevant short-term outcomes for T1DM, T2DM and GDM

include average glucose control (HbA1c), number of hypoglycemia and hyperglycemic events, and the time spent in hypoglycemia or hyperglycemia. Relevant long-term outcomes for T1DM and T2DM include the development of diabetes-related complications or comorbidities (e.g., kidney failure, blindness, amputation, heart attack, stroke), healthcare utilization (e.g., emergency department visits, hospitalizations), and diabetes medication use. For GDM, relevant outcomes also included maternal and infant health outcomes and the need for diabetic medications during pregnancy in women with GDM. Maternal health or pregnancy outcomes include: pre-eclampsia, pregnancy-induced hypertension, polyhydramnios, preterm delivery, premature rupture of membranes, induction of labor, cesarean delivery, lacerations at delivery, shoulder dystocia, maternal ICU admission, and T2DM development following pregnancy. Relevant infant health outcomes include: size at birth measured as large for gestational age, macrosomia, birth weight and adjusted birth weight percentile, prematurity, neonatal hypoglycemia, hyperbilirubinemia, respiratory distress syndrome, stillbirth, miscarriage, neonatal death, fetal injury during delivery, APGAR score < 7 [measure of newborn vigor at birth], congenital malformation, and NICU admission.

For key question #2, CHBRP included studies reporting adverse events related to the CGM device.

## Clinical Considerations

### *HbA1c*

Hemoglobin A1c (HbA1c) represents a patient's 90-day (or 12-week) blood sugar average. HbA1c is considered normal (no diabetes) when it is less than 5.6%. When a patient's HbA1c reaches 5.6% to 6.4%, a patient is considered pre-diabetic, and at 6.5% or greater, it is diagnostic for diabetes. Diabetes is characterized as being "well-controlled" when HbA1c remains less than 7% (or less than 8% in the elderly or those with specific complications) (ADA, 2017). In the studies identified in this review, HbA1c is typically reported as the mean difference (MD) between the CGM and SMBG groups, either measured at follow-up or as a change from baseline to follow-up. According to the FDA, "a difference of 0.4% HbA1c between CGM and SMBG groups is considered clinically significant... and is widely accepted in the field of diabetes research" (Langendam et al., 2012). Some studies, particularly non-U.S. studies, report HbA1c in mmol/L; CHBRP converted these values to mg/dL, which is standard in the U.S. HbA1c is traditionally not followed for patients with GDM (ACOG, 2017) so CHBRP did not expect studies of CGM use in GDM to report changes in HbA1c.

### *Hypoglycemia and hyperglycemia*

The normal concentration of glucose in the blood is typically between 80 to 100 mg/dL. Hypoglycemia occurs when a patient's blood glucose level drops below normal (typically below 70 mg/dL); severe hypoglycemia is typically defined as blood glucose below 40 mg/dL. Hyperglycemia occurs when blood glucose levels are too high, typically over 140 mg/dL. In the studies identified by this review, hypoglycemia and hyperglycemia are often reported as either event counts or as the time spent in either state (presented as a percentage of time or as the number of minutes per day). In the included research studies, severe hypoglycemia was most commonly defined as a hypoglycemic episode requiring the assistance of another person to resolve (by administering oral or injected sugar).



## Study Findings

### Findings Related to the Effectiveness of Continuous Glucose Monitors for Type 1 Diabetes Mellitus

#### *Retrospective CGM*

To determine the effectiveness of retrospective CGM use for patients with T1DM, this review relied on a 2012 Cochrane systematic review and meta-analysis, which included seven trials published prior to June 2011 comparing the use of retrospective CGM and SMBG (Langendam et al., 2012). In all of the trials, the CGM was used for 72-hours during multiple intervals during the study period. Two trials were conducted in adults aged 18 years and older (n, range, 75–128) and five were of children with average age ranging from 10 years to 15 years (n, range, 11–36). One trial of adults and two of children were conducted in the United States. CHBRP did not identify any randomized controlled trials of retrospective CGM use in T1DM patients published since 2011.

#### HbA1c (retrospective CGM in T1DM)

The Cochrane review concluded that retrospective CGM use for children (5 RCTs) and adults (2 RCTs) with T1DM did not result in statistically significant reductions in HbA1c compared with conventional SMBG (Langendam et al., 2012).

There is clear and convincing evidence that the use of retrospective CGMs in addition to SMBG for children and adults with T1DM is **not effective** in improving HbA1c compared to patients using SMBG alone. This conclusion is based on evidence from a well-conducted systematic review including seven RCTs (five conducted only in children and two in adults).

#### Hypoglycemia (retrospective CGM in T1DM)

The Cochrane review found that severe hypoglycemic events were rare for both adults and children with T1DM, and there was no significant difference in incidence of these events based on CGM or SMBG use (four trials in children, one in adults).

The Cochrane review only identified a single trial of children and a single trial of adults assessing the impact of CGM versus SMBG on time spent in hypoglycemia; the trial of children did not demonstrate any significant reduction in duration of hypoglycemia, whereas the trial of adults found that CGM users spent less time in hypoglycemia per day compared to SMBG users (MD, -2.3% of the time [95% CI, -3.6 to -0.9%]) (Langendam et al., 2012).

There is clear and convincing evidence that the use of retrospective CGMs in addition to SMBG for children with T1DM is **not effective** in decreasing the incidence of severe hypoglycemic events compared to patients using SMBG alone. This conclusion is based on evidence from a well-conducted systematic review including four trials of children.

There is limited evidence that the use of retrospective CGMs in addition to SMBG for adults with T1DM is **not effective** in decreasing the incidence of severe hypoglycemic events compared to patients using SMBG alone. This conclusion is based on evidence from a well-conducted systematic review including one trial of adults.

There is limited evidence that the use of retrospective CGMs in addition to SMBG for adults with T1DM is **effective** in decreasing the duration of hypoglycemia compared to patients using SMBG alone. This conclusion is based on evidence from a well-conducted systematic review including one trial of adults.

There is limited evidence that the use of retrospective CGMs in addition to SMBG for children with T1DM is **not effective** in decreasing the duration of hypoglycemia compared to patients using SMBG alone. This conclusion is based on evidence from a well-conducted systematic review including one trial of children.

#### Hyperglycemia and ketoacidosis (retrospective GCM in T1DM)

A single trial of adults and a single trial of children included in the Cochrane review found that the time spent in hyperglycemia per day was not significantly different between CGM and SMBG users (Langendam et al., 2012). The Cochrane review found that ketoacidosis was a rare event among children with T1DM, regardless of whether they used CGM or SMBG (two trials); no trials of adults reported on this outcome.

There is limited evidence that the use of retrospective CGMs in addition to SMBG for children and adults with T1DM is **not effective** in decreasing the duration of hyperglycemia compared to patients using SMBG alone. This conclusion is based on evidence from a well-conducted systematic review including one RCT in children and one RCT in adults.

There is limited evidence that the use of retrospective CGMs in addition to SMBG for children with T1DM is **not effective** in decreasing the incidence of ketoacidosis compared to patients using SMBG alone. This conclusion is based on evidence from a well-conducted systematic review including one RCT in children.

There is **insufficient evidence** to determine whether the use of retrospective CGM in addition to SMBG for adults with T1DM is effective in decreasing the incidence ketoacidosis compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

#### Development of long-term diabetes complications or comorbidities (retrospective GCM in T1DM)

None of the trials of retrospective CGM use in T1DM patients included in the Cochrane review measured the development of long-term diabetes complications or comorbidities. CHBRP did not identify any studies published since 2012 that examined these outcomes.

There is **insufficient evidence** to determine whether the use of retrospective CGMs in addition to SMBG for children or adults with T1DM is effective in reducing the development of diabetes-related complications or comorbidities compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

#### Healthcare and medication utilization (retrospective CGM in T1DM)

The 2012 Cochrane review did not assess the impact of retrospective CGM use on healthcare and medication utilization. CHBRP did not identify any studies published since 2012 that examined these outcomes.

There is **insufficient evidence** to determine whether the use of retrospective CGMs in addition to SMBG for children or adults with T1DM reduces the need for additional diabetes-related healthcare utilization (e.g., emergency department visits) or changes in medication use (e.g., changes in insulin dosage) compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

### *Real-time CGM*

To determine the effectiveness of real-time CGM on patients with T1DM, the medical effectiveness review relied primarily on the previously mentioned Cochrane review, as well as some meta-analyses reported in a 2012 AHRQ systematic review (Golden et al., 2012). The Cochrane review of real-time CGMs included fifteen unique trials; one trial conducted only in children (n=160), six trials conducted only in adults (n, range, 12 to 304), three trials conducted in both children (n, range, 18 to 156) and adults (n, range, 80 to 329) but provided results stratified by age, and five trials conducted in patients of all ages, but without stratification of results by age (n, 62 to 162). Five of the fifteen included trials were conducted in the U.S. The AHRQ review included nine unique trials of patients of all ages with T1DM (none of the trials included only children), eight of which were also in the Cochrane review; however, the AHRQ review reported the results of relevant meta-analyses which were not included in the Cochrane review. CHBRP presents the results of these additional analyses from the AHRQ systematic review. CHBRP also summarized the findings from eight unique randomized controlled trials published since 2011 comparing the effects of real-time CGM compared with SMBG in patients with T1DM (Battelino et al., 2012; Beck et al., 2017; Hermanns et al., 2014; Lind et al., 2017; Mauras et al., 2012; New et al., 2015; Rivelino et al., 2012; van Beers et al., 2016). Of the eight RCTs, only two (Battelino et al., 2012; Mauras et al., 2012) report some or all findings for children. As there is limited evidence related to the use of CGM in children, CHBRP also included one prospective cohort study comparing children (n=149; mean age, 11.8 years) using CGM and SMBG set in Israel (Rachmiel et al., 2015).

### *HbA1c (real-time CGM in T1DM)*

Only one of five trials of children included in the Cochrane review found that CGM users had significant reductions in HbA1c after three months of follow-up (MD, -0.24% [95% CI, -0.47% to -0.01%]) (Langendam et al., 2012). The AHRQ review meta-analyzed four trials including children and adolescents and found a significant improvement in HbA1c at follow-up among real-time CGM users compared with SMBG users (MD, -0.26 [95% CI, -0.5 to -0.1]) (Golden et al., 2012). The two trials of children or adolescents with T1DM published since 2011 report conflicting results. The trial by Battelino et al. (2012), which enrolled children aged 6 to 18 years (n=72), found a significant reduction in HbA1c between the CGM and SMBG users (MD, -0.46% [95% CI, -0.26% to -0.66%]; p<0.001), whereas the trial by Mauras et al. (2012), which enrolled children aged 4 to less than 10 years of age (n=146) did not find any significant difference between CGM and SMBG users. The prospective cohort study did not find any significant difference in HbA1c reductions between CGM and SMBG users (Rachmiel et al., 2015)

Of the five trials of adults or patients of all ages included in the Cochrane review, the reduction in HbA1c was statistically significant between the CGM and SMBG groups after three months in three trials (MD, range, -1.12% to -0.29%); after six months, two of those three trials still found a significant reduction (MD, range, -0.1% to -1.1%). One trial reported 12-month follow-up and found a sustained significant reduction between the CGM and SMBG group (MD, -0.60 [95% CI, -0.5% to -0.4%]) (Langendam et al., 2012). The 2012 AHRQ review meta-analyzed seven trials of patients of all ages, including some pediatric patients, and found a significant reduction in HbA1c at follow-up compared with baseline among adult real-time CGM users compared with SMBG users (mean difference [MD], -0.30 [95% CI, -0.37 to -0.22]; p=0.004). Among seven trials including adults published since 2011, four found statistically significant

improvements in HbA1c among CMG users compared with SMBG groups, ranging from -0.4% to -0.6% (Battelino et al., 2012; Beck et al., 2017; Lind et al., 2017; Riveline et al., 2012).

Some studies have examined the relationship between the percentage of time the CGM was used by the patient after starting monitoring (i.e., CGM use adherence) and reductions in HbA1c. Among adults, the AHRQ review found that increasing CGM adherence (use  $\geq 60\%$  of the time over the course of one week) was significantly associated with HbA1c improvement compared with patients using SMBG alone ( $p=0.022$ ) (Golden et al., 2012). Two of the recently published trials found that use of CGM more than 70% of the time was associated with significant reductions in HbA1c levels (range, -0.46% to -0.50%), while use less than 70% of the time was not associated with any significant reductions (Battelino et al., 2012; Lind et al., 2017). The study by Mauras et al. (2012) found significant reductions in HbA1c among pediatric patients using the CGM for six or more days per week ( $p=0.01$ ) compared to patients using the CGM less frequently.

There is **conflicting evidence** whether the use of real-time CGMs in addition to SMBG for children with T1DM can improve HbA1c compared to patients using SMBG alone. This conclusion is based on evidence from two well-conducted systematic reviews, two additional trials and one cohort study.

There is clear and convincing evidence that the use of real-time CGMs in addition to SMBG for adults with T1DM is **effective** in improving HbA1c compared to patients using SMBG alone. This conclusion is based on evidence from two well-conducted systematic reviews and seven additional trials.

There is clear and convincing evidence that adherence to the use of real-time CGMs in addition to SMBG at least 60% of the time **increases the effectiveness** for children and adults with T1DM. This conclusion is based on evidence from one well-conducted systematic review and three additional trials (one in children, two in adults).

### Hypoglycemia (real-time CGM in T1DM)

The Cochrane review found that severe hypoglycemic events were rare among children and adults with T1DM, and that there was no significant difference in the incidence of these events between CGM and SMBG users (three trials of children/adolescents and four of adults) (Langendam et al., 2012). The AHRQ meta-analysis looked at six trials (one trial included only children) and found no difference in the incidence of severe hypoglycemic events among those using real-time CGM compared with SMBG (pooled RR, 0.95 [95% CI, 0.53 to 1.69];  $p=0.86$ ) (Golden et al., 2012). Six trials published since 2011 (one in children and five in adults or all patients) measured the incidence of severe hypoglycemia; five trials found that the incidence of severe hypoglycemia was not significantly different between CGM and SMBG users (Battelino et al., 2012; Beck et al., 2017; Mauras et al., 2012; Riveline et al., 2012; van Beers et al., 2016); one trial did not assess the significance between CGM and SMBG users (Lind et al., 2017). The single cohort study of children did not find a significant difference in incidence of these events (Rachmiel et al., 2015).

The 2012 AHRQ systematic review meta-analyzed four studies (of adults or all ages) found no difference in the time spent in the hypoglycemic range (glucose level  $\leq 70$  mg/dL;  $p=0.52$ ). Five trials published since 2011 reported on the difference in percent of time per day spent in hypoglycemia between adult or all ages CGM users and SMBG users; all five trials found that CGM users spent significantly less time in hypoglycemia (MD, range -0.9% to -4.7% of time (Battelino et al., 2012; Beck et al., 2017; Hermanns et al., 2014; Lind et al., 2017; van Beers et al., 2016). A single study reported on duration of hypoglycemia among children only and did not find a significant difference in the percentage of time spent in hypoglycemia between CGM and SMBG groups ( $P=0.31$ ) (Mauras et al., 2012).

There is clear and convincing evidence that the use of real-time CGMs in addition to SMBG for children and adults with T1DM is **not effective** in decreasing the incidence of severe hypoglycemia compared to patients using SMBG alone. This conclusion is based on evidence from two well-conducted systematic reviews, six additional trials (one conducted only in children), and one additional cohort of children.

There is **conflicting evidence** whether the use of real-time CGMs in addition to SMBG for children and adults with T1DM can decrease the duration of hypoglycemia compared to patients using SMBG alone. This conclusion is based on one well-conducted systematic review and six additional trials (one conducted only in children).

### Hyperglycemia and ketoacidosis (real-time CGM in T1DM)

The Cochrane review included three trials (one including both children and adults and one of adults only) reporting duration of hyperglycemia, but none found any significant difference in time spent in hyperglycemia among real-time CGM users compared with SMBG users (Langendam et al., 2012). The AHRQ review meta-analyzed four studies of adults and found a significant decrease in the time spent in hyperglycemia (glucose level >180 mg/dL) (MD, -4.7% of the day [95% CI, -7.0% to -2.5%]) between the real-time CGM users and the SMBG group (Golden et al., 2012). Three of five trials published since 2012 reporting on hyperglycemia duration found that adult CGM users spent significantly less time in hyperglycemia per day compared with SMBG users (Battelino et al., 2012; Beck et al., 2017; van Beers et al., 2016) (the remaining two trials did not find any significant difference). A single study reporting duration of hyperglycemia in children did not find a significant difference between CGM and SMBG groups (Mauras et al., 2012).

The Cochrane review found that at six-month follow-up, the risk of ketoacidosis was not significantly decreased for CGM users compared to SMBG users (two trials with children and four with adults) (Langendam et al., 2012). Six of the trials published since 2011 (one with children and five with adults) reported the incidence of ketoacidosis and found that it was a rare event (Battelino et al., 2012; Beck et al., 2017; Mauras et al., 2012; Rivelino et al., 2012; van Beers et al., 2016); only one trial with adults (Battelino, 2012) assessed for significance and found no difference between CGM and SMBG users. The single cohort study published since 2011 did not find a significant difference in the incidence of ketoacidosis between CGM and SMBG users (Rachmiel et al., 2015).

There is limited evidence that the use of real-time CGMs in addition to SMBG for children with T1DM is **not effective** in decreasing the duration of hyperglycemia compared to patients using SMBG alone. This conclusion is based on evidence from one well-conducted systematic review including one trial with children and one additional trial with children.

There is a preponderance of evidence from studies with strong research designs that the use of real-time CGMs in addition to SMBG for adults with T1DM is **effective** in decreasing the duration of hyperglycemia compared to patients using SMBG alone. This conclusion is based on evidence from two systematic reviews and five additional trials with adults.

There is clear and convincing evidence that the use of real-time CGMs in addition to SMBG for children and adults with T1DM is **not effective** in reducing the incidence of ketoacidosis compared to patients using SMBG alone. This conclusion is based on evidence from one well-conducted systematic review, five additional trials (one conducted only in children), and one additional cohort study of children.



### Development of long-term diabetes complications or comorbidities (real-time GCM in T1DM)

There is **insufficient evidence** to determine whether the use of real-time CGMs in addition to SMBG for children and adults with T1DM is effective in reducing the development of diabetes-related complications or comorbidities compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

### Healthcare and medical utilization (real-time CGM in T1DM)

The 2012 Cochrane review did not assess the impact of retrospective CGM use on healthcare and medication utilization. One trial (n=52) published since 2012 reported that some adult CGM and SMBG users had episodes of severe hypoglycemia resulting in a seizure or coma or a hospitalization; however, the event rates were equal across both groups (van Beers et al., 2016).

Of four trials reporting changes in total daily insulin dose between CGM and SMBG users, three did not find any difference (Battelino et al., 2012; Beck et al., 2017; Mauras et al., 2012) and one study found a mean difference of -0.02 units/kg per day (p=0.01) (on top of a baseline of 0.69 units/kg per day among CGM users) at the end of the 69-week follow-up (Lind et al., 2017). No trials or cohort studies of children with T1DM using real-time CGM measuring these outcomes were identified.

There is limited evidence that the use of real-time CGMs in addition to SMBG for adults with T1DM is **not effective** in decreasing healthcare utilization compared to patients using SMBG alone. This conclusion is based on evidence from a single trial.

There is **conflicting evidence** whether the use of real-time CGMs in addition to SMBG for adults with T1DM results in medication changes that would not have otherwise occurred compared to patients using SMBG alone. This conclusion is based on evidence from four trials.

There is **insufficient evidence** to determine whether the use of real-time CGMs in addition to SMBG for children with T1DM results in changes in healthcare and medication use compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

## Findings Related to the Effectiveness of Continuous Glucose Monitors for Type 2 Diabetes Mellitus

### *Retrospective CGM*

The medical effectiveness review identified two small trials (Blackberry et al., 2014; Cosson et al., 2009) and one retrospective cohort study (Kim et al., 2014) comparing the effects of retrospective CGM use versus SMBG in T2DM. The trial by Cosson et al. was set in France and conducted among adult patients (n=25; mean age, 57.2 years). Patients were randomized to having their CGM data known to both patient and provider, or to have their CGM data not disclosed to the patient (masked) with the patient completing SMBG. The trial by Blackberry et al. was set in Australia and randomized adult patients (n=92; mean age, 59 years) to retrospective CGM or SMBG. Patients randomized to the CGM group used the monitor for a 7-day period at baseline, 12 weeks, and 24 weeks. Both of these trials were industry sponsored. A cohort study by Kim et al. (2014), conducted in Korea, was a retrospective medical records review of 65 adult retrospective CGM users (mean age, 58.3 years) and 301 matched controls (mean age, 62.5 years). All patients used the CGM for 3 days before returning to the physician for data review. No trials or cohort studies of children with T2DM using retrospective CGM were identified.

### HbA1c (retrospective CGM in T2DM)

Neither trial demonstrated a significant improvement in HbA1c among CGM users compared to conventional SMBG. In contrast, the cohort study found that CGM users had significant improvements in their HbA1c levels compared with controls at 3 months (7.4% vs 7.9%;  $p=0.001$ ) and 6 months (7.3% vs 7.7%;  $p=0.01$ ) post-intervention (Kim et al., 2014). No trials or cohort studies of children with T2DM using retrospective CGM were identified.

There is **conflicting evidence** whether the use of retrospective CGMs in addition to SMBG for adults with T2DM improves HbA1c compared to patients using SMBG alone. This conclusion is based on evidence from two trials and one retrospective cohort study.

There is **insufficient evidence** to determine whether the use of retrospective CGMs in addition to SMBG for children with T2DM improves HbA1c compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

### Hypoglycemia (retrospective CGM in T2DM)

Neither trial found that retrospective CGM use resulted in a significant reduction in the incidence of severe hypoglycemic events among adults with T2DM (Blackberry et al., 2014; Cosson et al., 2009).

The trial by Cosson et al. did not demonstrate any significant reduction in duration of hypoglycemia after 3 months of follow-up; the trial by Blackberry et al. did not report this outcome.

No trials or cohort studies of children with T2DM using retrospective CGM were identified.

There is limited evidence that the use of retrospective CGMs in addition to SMBG for adults with T2DM is **not effective** in decreasing the incidence of severe hypoglycemic events compared to patients using SMBG alone. This conclusion is based on evidence from two trials.

There is limited evidence that the use of retrospective CGMs in addition to SMBG for adults with T2DM is **not effective** in decreasing the duration of hypoglycemia compared to patients using SMBG alone. This conclusion is based on evidence from a single trial.

There is **insufficient evidence** to determine whether the use of retrospective CGMs in addition to SMBG for children with T2DM reduces the incidence of severe hypoglycemic events or duration of hypoglycemia compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

### Hyperglycemia and ketoacidosis (retrospective CGM in T2DM)

A single trial did not demonstrate any significant reduction in duration of hyperglycemia among adults with T2DM after 3 months of follow-up (Cosson et al., 2009).

Neither of the trials or the cohort study reported incidence of ketoacidosis.

No trials or cohort studies of children with T2DM using retrospective CGM were identified.

There is limited evidence that the use of retrospective CGMs in addition to SMBG for adult patients with T2DM is **not effective** in decreasing the duration of hyperglycemia compared to patients using SMBG alone. This conclusion is based on evidence from a single trial.

There is **insufficient evidence** to determine whether the use of retrospective CGMs in addition to SMBG for children and adults with T2DM reduces the incidence of ketoacidosis compared to patients using SMBG alone. There is also **insufficient evidence** to determine whether the use of CGMs in addition to SMBG for children with T2DM reduces the duration of hyperglycemia compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

#### Development of long-term diabetes complications or comorbidities (retrospective CGM in T2DM)

There is **insufficient evidence** to determine whether the use of retrospective CGMs in addition to SMBG for children and adults with T2DM is effective in reducing the development of diabetes-related complications or comorbidities compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

#### Healthcare and medical utilization (retrospective CGM in T2DM)

The trial by Blackberry et al. (2014) found that retrospective CGM users decreased the number of oral diabetes medications they were taking over the 24-week follow-up compared to SMBG users, primarily due to patients decreasing from two to one medication ( $p=0.015$ ). The retrospective cohort by Kim et al. (2014) study found that there were significant differences in recommended medication changes between the CGM and SMBG users. Among insulin-treated CGM users, 60% experienced changes to their treatment plan (e.g., changing insulin dose, adding or changing oral medications) compared to 15.4% of insulin-treated SMBG users ( $p=0.001$ ). Likewise, 80% of non-insulin treated CGM users added or changed oral medications compared to 38.6% of non-insulin treated SMBG users ( $p=0.001$ ) (Kim et al., 2014).

No trials or cohort studies of children with T2DM using retrospective CGM were identified.

There is limited evidence that the use of retrospective CGMs in addition to SMBG for adults with T2DM is **effective** in informing insulin and diabetes medication utilization that would not have occurred based on SMBG use alone. This conclusion is based on evidence from one trial and one retrospective cohort study.

There is **insufficient evidence** to determine whether the use of retrospective CGMs in addition to SMBG for children with T2DM results in changes to insulin or diabetes medication use compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

#### Real-time CGM

The medical effectiveness review identified three RCTs examining the effectiveness of real-time CGM in T2DM. All three trials were conducted in adults (aged 18 years or older); two studies were set in Europe and were industry sponsored (Ajjan et al., 2016; New et al., 2015), and one ( $n=100$ ) was conducted in a U.S. military population and industry sponsored with one year follow-up (Ehrhardt et al., 2011; Vigersky et al., 2012). All three trials assessed the use of real-time CGM compared with SMBG; the study by New et al. compared real-time CGM with or without alarms versus SMBG. CHBRP did not identify any trials or cohort studies of real-time CGM use in children.



### HbA1c (real-time CGM in T2DM)

All three trials reported on the difference in HbA1c levels between the CGM and SMBG users at follow-up. The trial by Aijan et al. (n=87) did not find a significant reduction in HbA1c between users after 100 days (Aijan et al., 2016). The trial by New et al. (n=145) did not find any significant reductions between the use of CGM with or without alarms compared with SMBG after 80-100 days follow-up (New et al., 2015). After 12-weeks of CGM use, Erhardt et al. found a statistically significant reduction of 0.5% between the CGM and SMBG users (p=0.006); this difference remained statistically significant for the remaining 40 weeks of follow-up, despite the CGM arm crossing over to SMBG use after 12 weeks (Erhardt et al., 2011; Vigersky et al., 2012). CHBRP did not identify any trials or cohort studies of real-time CGM use in children.

There is **conflicting evidence** whether the use of real-time CGMs in addition to SMBG for adults with T2DM improves HbA1c compared to patients using SMBG alone. This conclusion is based on evidence from three trials.

There is **insufficient evidence** to determine whether the use of real-time CGMs in addition to SMBG for children with T2DM improves HbA1c compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

### Hypoglycemia (real-time CGM in T2DM)

The trial by Aijan et al. did not find any significant difference in the incidence of severe hypoglycemia or the time spent in hypoglycemia between the CGM and SMBG groups, or when comparing the CGM group at baseline versus follow-up (Aijan et al., 2016). The trial by New et al. assessed whether the use of CGM (with or without alarms) reduced the time spent outside of the goal glucose range (71 to 180 mg/dL) compared with SMBG, but did not find a significant difference (CGM with alarm vs. SMBG, p=0.77; CMG without alarm vs. SMBG, p=0.76) (New et al., 2015).

CHBRP did not identify any trials or cohort studies of real-time CGM use in children.

There is limited evidence that the use of real-time CGMs in addition to SMBG for adults with T2DM is **not effective** in reducing the incidence of severe hypoglycemic events. This conclusion is based on evidence from a single trial.

There is limited evidence that the use of real-time CGMs in addition to SMBG for adults with T2DM is **not effective** in decreasing the duration of hypoglycemia compared to patients using SMBG alone. This conclusion is based on evidence from two trials.

There is **insufficient evidence** to determine whether the use of real-time CGMs in addition to SMBG for children with T2DM reduces the incidence of severe hypoglycemic events or decreases the duration of hypoglycemia compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

### Hyperglycemia and ketoacidosis (real-time CGM in T2DM)

The trial by Aijan et al. did not find any significant difference in the time spent in hyperglycemia between the CGM and SMBG groups, or when comparing the CGM group at baseline versus follow-up (Aijan et al., 2016). As stated above, the trial by New et al. did not find any significant difference between real-time CGM and SMBG users in the time spent outside of the goal glucose range (71 to 180 mg/dL) (New et al., 2015).

CHBRP did not identify any trials or cohort studies of real-time CGM use in children.

CHBRP also did not identify any studies reporting the incidence of ketoacidosis in CGM versus SMBG users.

There is limited evidence that the use of real-time CGMs in addition to SMBG for adults with T2DM is **not effective** in reducing the duration of hyperglycemia compared to patients using SMBG alone. This conclusion is based on evidence from two trials.

There is **insufficient evidence** to determine whether the use of real-time CGMs in addition to SMBG in children with T2DM reduces the duration of hyperglycemia compared to patients using SMBG alone. There is also **insufficient evidence** to determine whether the use of real-time CGMs in addition to SMBG in children or adults with T2DM reduces the incidence of ketoacidosis compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

#### Development of long-term diabetes complications or comorbidities (real-time CGM in T2DM)

There is **insufficient evidence** to determine whether the use of real-time CGMs in addition to SMBG for children and adults with T2DM is effective in reducing the development of diabetes-related complications or comorbidities compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

#### Healthcare and medical utilization (real-time CGM in T2DM)

There is **insufficient evidence** to determine whether the use of real-time CGMs in addition to SMBG for children and adults with T2DM is effective in reducing diabetes-related healthcare and medical utilization compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

### Findings Related to the Effectiveness of Continuous Glucose Monitors for Pregnant Women with Gestational Diabetes Mellitus

#### *Retrospective CGM*

The medical effectiveness review identified two trials assessing the effects of retrospective CGM in patients with GDM on their pregnancy outcomes (Kestila et al., 2007; Yu et al., 2014). These studies used CGM to monitor glucose over a short period near the start of the third trimester and then provide information and treatment adjustments to the patients based on the data. Neither trial was conducted on a U.S. population (China [n=336] and Finland [n=73]). The medical effectiveness review also identified two prospective cohort studies assessing the effects of retrospective CGM in patients with GDM (Chen et al., 2003; McLachlan et al., 2007). These studies included small sample sizes of patients with GDM and evaluated glucose variability and the ability of CGM to provide additional glucose information compared to SMBG. The Chen et al. study had 10 patients in California and 47 patients in Israel; the McLachlan et al. study was conducted in Australia on 37 patients.

### HbA1c (retrospective CGM in GDM)

There is **insufficient evidence** to determine whether the use of retrospective CGMs in addition to SMBG for patients with GDM is effective in improving HbA1c compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

### Hypoglycemia (Retrospective CGM in GDM)

The trial by Yu et al. assessed the time spent in hypoglycemia in minutes per day and as number of patients experiencing hypoglycemia for longer than 30 minutes among 336 patients with GDM, randomized into two groups. One group used SMBG plus 72-hour CGM at baseline (time of GDM diagnosis) and then every 2 to 4 weeks through week 5. The other group used conventional SMBG plus wore a CGM at baseline and at week 5, with the data masked to patient and provider during the study data. Diabetes treatment regimens were adjusted based on the data available to the providers (CGM plus SMBG vs. SMBG only). The authors found that in the CGM group compared to the SMGB-only group (with masked CGM), there were significantly shorter durations of hypoglycemia (0% of the time [inter-quartile range (IQR), 0% to 0%] versus 0% of the time [IQR, 0% to 1.8%]  $p < 0.001$ ) at 4-week follow-up. In the CGM group, 3.4% of patients experienced hypoglycemia for longer than 30 minutes compared to the 19.4% of patients in the SMBG group (Yu et al., 2014). No studies assessed severe hypoglycemic events (those requiring the care of another person to resolve).

There is limited evidence that the use of retrospective CGMs in addition to SMBG for patients with GDM is **effective** in decreasing the duration of hypoglycemia compared to patients using SMBG alone. This conclusion is based on evidence from a single trial.

There is **insufficient evidence** to determine whether the use of retrospective CGMs in addition to SMBG for patients with GDM reduces the incidence of severe hypoglycemic events compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

### Hyperglycemia (retrospective CGM in GDM)

The trial by Yu et al. assessed time spent in hyperglycemia among 336 patients with GDM, randomized into two groups. In the CGM group compared to the SMBG group (with masked CGM), the study found significantly shorter durations of hyperglycemia (0% of the time [IQR, 0% to 1.8%] versus 4.3% of the time [IQR, 0% to 79.3%]  $p < 0.001$ ) at 4 week follow-up (Yu et al., 2014).

There is **limited evidence** that the use of retrospective CGMs in addition to SMBG for patients with GDM is effective in decreasing the duration of hyperglycemia compared to patients using SMBG alone. This conclusion is based on evidence a single trial.

### Healthcare and medical utilization (retrospective CGM in GDM)

Two trials found that CGM use led to the addition of anti-diabetic medications to control patient blood glucose that would not have been added based on SMBG data alone. The trial by Yu et al. (2014) found that 21 patients wearing the CGM had insulin added due to findings on CGM, compared to 20 patients in the CGM group from SMBG findings alone, and 23 patients in the SMBG group (41 total patients on insulin in CGM group vs. 23 in the SMBG group,  $p < 0.001$ ) (Yu et al., 2014). The Kestila et al. trial randomized patients to either a 48 hour CGM after GDM diagnosis or SMBG only group found that 31% of patients with CGM required anti-diabetic medication (insulin and/or metformin) to adequately control

blood sugars based on both CGM and SMBG data compared to 8% of patients based on SMBG data alone ( $p=0.0149$ ) (Kestila et al., 2007). Two observational studies (Chen et al., 2003; McLachlan et al., 2007) found that 72-hour retrospective CGM use could detect hypo- and hyperglycemia undetected by SMBG, and be used to adjust treatment regimens. In the Chen et al. study, 46 out of 57 patients had their treatment regimen changed based on CGM data, and in the McLahan et al. study, providers used the additional CGM data to make treatment decisions for 56% of the 37 patients with GDM.

The trial by Yu et al. (2014) did not demonstrate any difference in need for NICU care after birth.

There is limited evidence that the use of retrospective CGMs in addition to SMBG for patients with GDM is **effective** in informing anti-diabetic medication utilization that would not have occurred based on SMBG use alone. This conclusion is based on evidence from two trials and two observational studies.

There is limited evidence that the use of retrospective CGMs in addition to SMBG for patients with GDM is **not effective** at reducing NICU utilization for infants of mothers with GDM. This conclusion is based on evidence from one trial.

### Maternal health outcomes (retrospective CGM in GDM)

One trial assessed relevant pregnancy outcomes including pre-eclampsia and cesarean section rates (Yu et al., 2014). Yu et al. found that pre-eclampsia was less common in the CGM group than the SMBG group (3.4% vs. 10.1%;  $p=0.019$ ). This study also did not find a significant difference in overall cesarean section rate, although it did demonstrate a lower incidence of primary (first time) cesarean sections for those using CGM compared to SMBG (34.7% vs. 46.6%;  $p=0.028$ ) (Yu et al., 2014).

No studies assessed rates of T2DM following pregnancy.

There is limited evidence that the use of retrospective CGMs in addition to SMBG for patients with GDM is **effective** in improving maternal health outcomes through lower rates of pre-eclampsia and primary cesarean sections compared to patients using SMBG alone. This conclusion is based on evidence from one trial.

There is **insufficient evidence** to determine whether the use of retrospective CGMs in addition to SMBG for patients with GDM is effective in reducing the development of T2DM postpartum compared to patients using SMBG alone. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

### Infant health outcomes (retrospective CGM in GDM)

The Yu trial assessed relevant infant health outcomes after 3 to 4 uses of 72-hour CGM, over a 5-week period, with the patients' diabetes treatment adjusted based on CGM results after each use (Yu et al., 2014). Fewer adverse fetal outcomes were seen in the CGM group compared to the SMBG group, including fewer large infants (measured as large for gestational age) (13.7% vs. 25.8%;  $p=0.01$ ), macrosomia (4.1% vs. 10.8%;  $p=0.025$ ), birth weight (3138 grams vs. 3345 grams;  $p<0.001$ ) and adjusted birth weight percentile (66<sup>th</sup> percentile vs. 82<sup>nd</sup> percentile;  $p<0.001$ ), and fewer infants with prematurity (4.8% vs. 11.8%;  $p=0.024$ ), neonatal hypoglycemia (5.5% vs. 14%;  $p=0.011$ ), hyperbilirubinemia (2.7% vs. 9.7%;  $p=0.012$ ), and respiratory distress syndrome (1.4% vs. 5.9%;  $p=0.034$ ) (Yu et al., 2014).

There is **limited evidence** that the use of retrospective CGMs in addition to SMBG for patients with GDM is **effective** in improving infant health outcomes (large for gestational age, macrosomia, birth weight, adjusted birth weight percentile, prematurity, neonatal hypoglycemia, hyperbilirubinemia, respiratory distress syndrome) compared to patients using SMBG alone. This conclusion is based on evidence from a single trial.

### *Real-time CGM*

The medical effectiveness review identified a single moderately sized trial (n=122) and no cohort studies assessing the use of real-time CGM for patients with GDM (Alfadhli et al., 2016). This trial, conducted in Saudi Arabia, examined 122 patients with GDM, 60 of whom were randomized to real-time CGM for an average of 3 days, and 62 to SMBG, at 24 to 28 weeks gestation. The CGM group was encouraged to follow CGM output and respond to correct hypo- and hyperglycemia. An important limitation of this study is that it used real-time CGM for a single short period (an average of 3 days) and at one time during the pregnancy, compared to the typical long-term use of real-time CGM. This limitation was used by CHBRP to downgrade the level of evidence from “limited” to “insufficient” for that study.

### *HbA1c (real-time CGM in GDM)*

Alfadhli et al. (2016) found no significant difference in HbA1c at the end of the pregnancy between the CGM and SMBG groups.

There is **insufficient evidence** to determine whether the use of real-time CGMs in addition to SMBG for patients with GDM is effective in improving HbA1c compared to patients using SMBG alone. This conclusion is based on evidence from a single trial with a weak research design.

### *Hypoglycemia (real-time CGM in GDM)*

Among CGM users, Alfadhli et al. (2016) assessed the time spent in hypoglycemia between the 1st day of CGM use and the last day of CGM (average 3 days of use) use and found no significant difference.

There is **insufficient evidence** to determine whether the use of real-time CGMs in addition to SMBG for patients with GDM is effective in reducing the duration of hypoglycemia compared to patients using SMBG alone. This conclusion is based on evidence from a single trial with a weak research design.

### *Hyperglycemia (real-time CGM in GDM)*

Among CGM users, Alfadhli et al. (2016) assessed the time spent hyperglycemic states between the 1st day of CGM use and the last day of CGM use and found no significant difference. The difference in mean fasting and post-meal glucose between the CGM and SMBG groups was not significant at the end of pregnancy. The authors reported a statistically significant improvement in glucose variability (range from highest to lowest blood sugar reading) as measured by the average glucose reading and standard deviation of the average glucose reading from the first to the last day of CGM use (average 3 days of use) ( $p=0.016$  and  $p=0.034$ ).

There is **insufficient evidence** to determine whether the use of real-time CGMs in addition to SMBG for patients with GDM is effective in reducing the duration of hyperglycemia compared to patients using SMBG alone. This conclusion is based on evidence from a single trial with a weak research design.



### Maternal health outcomes (real-time CGM in GDM)

Alfadhli et al. (2016) assessed various maternal health outcomes, including polyhydramnios, preterm delivery, premature rupture of membranes, induction of labor, cesarean delivery, lacerations, shoulder dystocia and maternal ICU admission, but did not find significant differences in any of these outcomes between the CGM and SMBG groups. T2DM development following pregnancy was not assessed.

There is **insufficient evidence** to determine whether the use of real-time CGMs in addition to SMBG for patients with GDM is effective in improving maternal health outcomes compared to patients using SMBG alone. This conclusion is based on evidence from a single trial with a weak research design.

### Infant health outcomes (real-time CGM in GDM)

Alfadhli et al. (2016) found no significant difference between the CGM and SMBG groups across numerous outcomes, including stillbirth, miscarriage, neonatal death, preterm birth, fetal injury during delivery, APGAR score <7 (measure of newborn vigor at birth), macrosomia, birth weight, neonatal hypoglycemia, neonatal hyperbilirubinemia, congenital malformation, respiratory distress syndrome in infant and NICU admission.

There is **insufficient evidence** to determine whether the use of real-time CGMs in addition to SMBG for patients with GDM is effective in improving infant health outcomes compared to patients using SMBG alone. This conclusion is based on evidence from a single trial with a weak research design.

### Healthcare and medical utilization (real-time CGM in GDM)

Alfadhli et al. (2016) did not find any significant difference in insulin use (total daily dose or number of patients needing insulin) between patients with GDM using real-time CGM and those using SMBG.

There is **insufficient evidence** to determine whether the use of real-time CGMs in addition to SMBG for patients with GDM results in insulin changes compared to patients using SMBG alone. This conclusion is based on evidence from a single trial with a weak research design.

## Findings Related to the Harms of Continuous Glucose Monitors for Patients with Type 1, Type 2, or Gestational Diabetes

Six trials of T1DM and T2DM patients recorded adverse events occurring during the study period; of those trials, only two reported events related to the device. New et al. (2015) reported that 7.6% of patients (12/157) reported some type of sensor-site insertion issues, primarily redness (26%), bleeding (21%), or itching (15%). Lind et al. (2017) reported that one patient discontinued CGM use due to an allergic reaction. While 48% of patients in the study by Aijan et al. (2016) experienced an adverse event, none of those were serious device-related events; however, 87% of patients (48/56) experienced some sort of sensor-site insertion issue. For GDM patients, Alfadhli et al. (2016) reported no major side effects and only mild side effects of mild skin redness or irritation at the insertion site. The authors report 10% did not find the system acceptable due to anxiety related to constant glucose tracking and discomfort lying down on sensors placed on the upper outer buttocks were described (Alfadhli et al., 2016). The trial by Yu et al. (2014) found that three sensors had to be replaced due to technical issues, and saw no skin irritation or infection.

The purpose of CGM use is to attempt to achieve tighter glycemic control, and a potential harm of doing so is an increase in the incidence of severe hypoglycemic events or duration of hypoglycemia; however,

no trials of either retrospective or real-time CGM use in children or adults found an increase in these events among CGM users.

There is clear and convincing evidence that the use of either retrospective or real-time CGMs are not associated with an increase in severe hypoglycemia events, duration of hypoglycemia, or serious device-related harms.

There is a preponderance of evidence from studies with strong research designs that the use of either retrospective or real-time CGMs can cause minor insertion site symptoms, such as skin irritation.

The *Public Health Impacts* section presents a further discussion of additional factors contributing to patient satisfaction and quality of life associated with the use of continuous glucose monitors.

## Summary of Findings

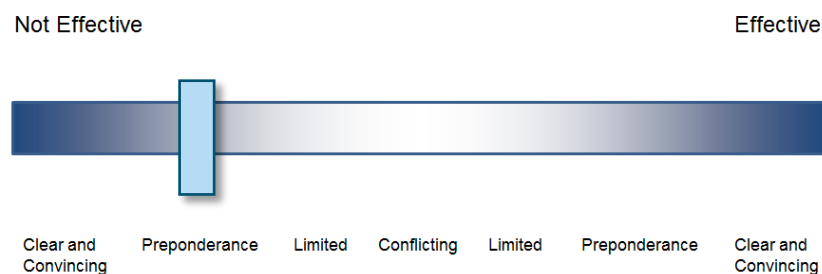
The charts in this section summarize CHBRP’s findings regarding the strength of the evidence for the effectiveness of CGMs as specified by AB 447. Separate charts are presented for each modality (retrospective vs. real-time) by type of diabetes for the overall effectiveness of CGMs. The title of the chart indicates the type of monitor and type of diabetes. The statement under the heading “Conclusion” presents CHBRP’s overall conclusion regarding the strength of evidence about the effectiveness of CGMs, and the specific strength of evidence for each outcome measured follows in the below paragraph. When CHBRP concludes that there is clear and convincing, preponderance, limited, or conflicting evidence, the placement of the vertical bar indicates the strength of the evidence. If CHBRP concludes that evidence is insufficient, a grayed-out chart that states “Insufficient Evidence” will be presented.

**Figure 5.** Retrospective Continuous Glucose Monitors for Type 1 Diabetes Mellitus

### Conclusion

CHBRP concludes that there is a preponderance of evidence based on one well-conducted systematic review of 7 RCTs that the use of retrospective CGMs for patients with type 1 diabetes mellitus are not effective.

There is limited evidence based on one RCT included in the well-conducted systematic review that retrospective CGMs can decrease the duration of hypoglycemia among adults with T1DM. However, the evidence suggests that retrospective CGM use in patients with T1DM has no effect on HbA1c, the incidence of severe hypoglycemic events, the duration of hyperglycemia, and the duration of hypoglycemia and incidence of ketoacidosis in children; the level of evidence varied from limited to clear and convincing evidence demonstrating lack of effectiveness depending on the outcome assessed. In addition, no RCTs have assessed the impact of retrospective CGMs on the incidence of ketoacidosis in adults, the development of long-term complications, or on healthcare and medication utilization.

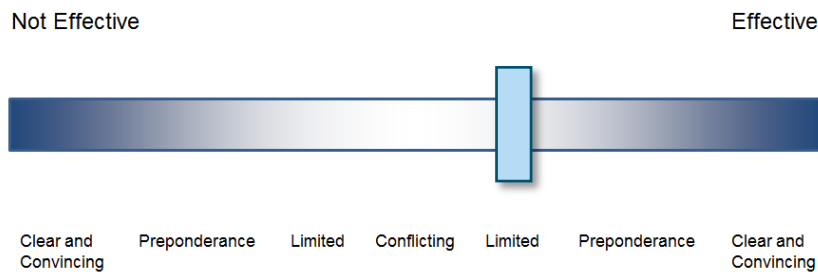


**Figure 6.** Real-Time Continuous Glucose Monitors for Type 1 Diabetes Mellitus

**Conclusion**

CHBRP concludes that there is limited evidence based on two well-conducted systematic reviews, 8 additional RCTs and one cohort study of children that the use of real-time CGMs for patients with type 1 diabetes mellitus is effective.

There is clear and convincing evidence based on two well-conducted systematic reviews and 7 additional RCTs that real-time CGM use can improve HbA1c and a preponderance of evidence from two systematic reviews and 5 additional RCTs that it can decrease the duration of hyperglycemia among adults with T1DM. However, the evidence suggests that real-time CGM use in patients with T1DM has no effect on decreasing the incidence of severe hypoglycemic events or ketoacidosis, decreasing the duration of hyperglycemia in children, or decreasing unnecessary healthcare utilization in adults; the level of evidence varied from limited to clear and convincing evidence demonstrating lack of effectiveness depending on the outcome assessed. There is conflicting evidence as to whether real-time CGMs are effective in improving HbA1c in children, decreasing the duration of hypoglycemia, or resulting in effective medication changes in adults. In addition, no RCTs have assessed the impact of real-time CGMs on the development of long-term complications in children and adults or healthcare and medication utilization in children.



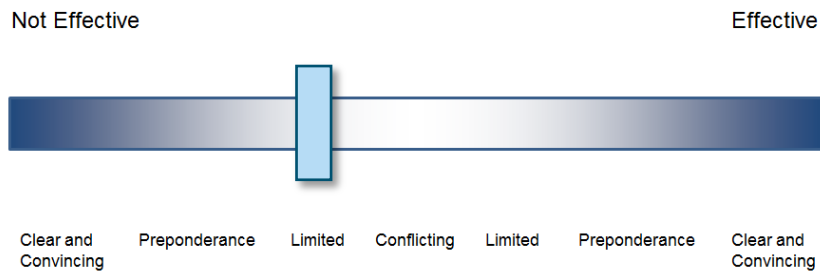


**Figure 7. Retrospective Continuous Glucose Monitors for Type 2 Diabetes Mellitus**

**Conclusion**

CHBRP concludes that there is limited evidence based on two RCTs and one cohort study that the use of retrospective CGMs for patients with type 2 diabetes mellitus are not effective.

There is limited evidence based on one RCT and one cohort study that retrospective CGM use among adults with T2DM can inform insulin and diabetes medication utilization that would not have otherwise occurred based on self-monitoring of blood glucose alone. However, there is limited evidence suggesting that retrospective CGM use in adults with T2DM has no effect on the incidence of severe hypoglycemic events and the duration of hypoglycemia or hyperglycemia. There is conflicting evidence as to whether the intervention improves HbA1c. In addition, no RCTs have assessed the impact of retrospective CGMs the incidence of ketoacidosis, development of long-term complications, or healthcare utilization among adults; no RCTs have assessed the impact of retrospective CGMs in children with type 2 diabetes.

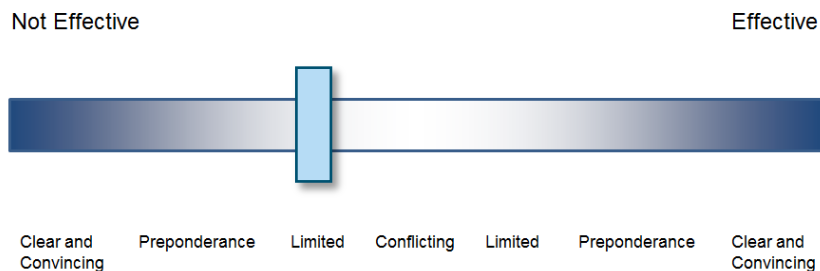


**Figure 8. Real-Time Continuous Glucose Monitors for Type 2 Diabetes Mellitus**

**Conclusion**

CHBRP concludes that there is limited evidence based on three RCTs that the use of real-time CGMs for patients with type 2 diabetes mellitus is not effective.

There is limited evidence based on three RCTs that real-time CGMs for adults with T2DM has no effect decreasing the incidence of severe hypoglycemic events or reducing the duration of hypoglycemia or hyperglycemia. There is conflicting evidence as to whether real-time CGMs result in improvements in HbA1c among adults. In addition, no RCTs have assessed the impact of real-time CGMs use in adults on the incidence of ketoacidosis, development of long-term complications, or on healthcare and medication utilization; no RCTs have assessed the impact of real-time CGMs in children with T2DM.

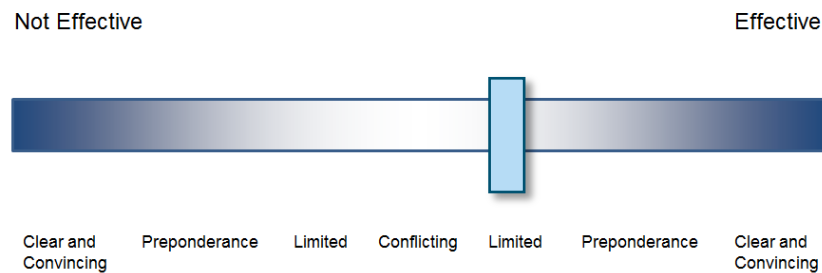


**Figure 9.** Retrospective Continuous Glucose Monitors for Gestational Diabetes Mellitus

**Conclusion**

CHBRP concludes that there is limited evidence based on two RCTs and two cohort studies that the use of retrospective CGMs for patients with gestational diabetes mellitus is effective.

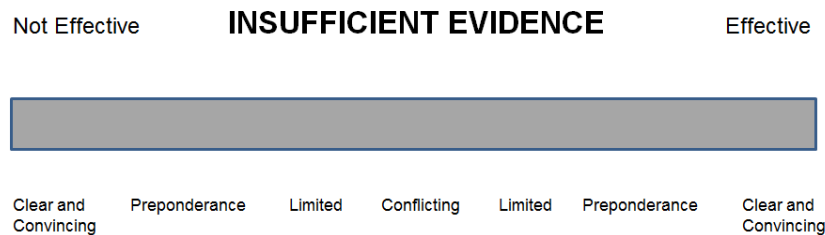
There is limited evidence that retrospective CGM use for patients with GDM can reduce the duration of hypoglycemia and hyperglycemia, inform insulin and diabetes medication utilization that would not have otherwise occurred based on self-monitoring of blood glucose alone, and improve some maternal outcomes, including lower rates of pre-eclampsia, primary cesarean sections, and infant health outcomes, including large for gestational age, macrosomia, birth weight, adjusted birth weight percentile, prematurity, neonatal hypoglycemia, hyperbilirubinemia, respiratory distress syndrome. However, there is limited evidence suggesting that retrospective CGM use in patients with GDM is not effective at reducing NICU utilization for infants of mothers with GDM. In addition, no RCTs have assessed the impact of retrospective CGMs on HbA1c, incidence of severe hypoglycemic events, or the development of T2DM postpartum.



**Figure 10.** Real-Time Continuous Glucose Monitors for Gestational Diabetes Mellitus

**Conclusion**

CHBRP concludes that there is insufficient evidence to assess whether real-time CGMs are effective for patients with gestational diabetes mellitus. This conclusion is based on a single RCT with a weak study design.



## **BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS**

AB 447 would require all DMHC-regulated Medi-Cal managed care plans, Medi-Cal County Organized Health Systems (COHS), and the DHCS operated fee-for-service (FFS) Medi-Cal program to cover 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).

This section reports the potential incremental impacts of AB 447 on estimated baseline benefit coverage, utilization, and overall cost. CHBRP assumes that any new use of CGMs postmandate will be approximately similar to the use of CGMs in the commercial market, where CGMs are already covered by the majority of both DMHC- and CDI-regulated commercial health plans, for the same population with diabetes, adjusting for the underlying differences in diabetes prevalence, severity (i.e., the level of uncontrolled diabetes), and cost-sharing requirements. These assumptions were due to the lack of data on actual use of CGM by Medi-Cal enrollees in managed care plans, where the benefit is covered by most plans. Medi-Cal enrollees have a higher diabetes prevalence rate (by 95%) and a higher rate of uncontrolled diabetes (by 44.4%) when compared to commercially insured populations (CHIS, 2017a; CHIS, 2017c; California Right Care Initiative, 2015). CHBRP adjusted the MarketScan analysis to account for the disease prevalence and severity differences in Medi-Cal to estimate baseline and postmandate use and spending. CHBRP also assumes that the cost per unit of CGMs paid for by Medi-Cal health plans or the fee-for-service Medi-Cal program will be lower than the cost per unit in the commercial insurance market based on known differences between the fee schedules of the different insurance types (Hunt et al., 2001).

Current coverage of CGM for the treatment and management of diabetes was determined by a survey of the largest (by enrollment) providers of privately funded health insurance and Medi-Cal managed care in California. Based on consultation with a billing code expert from the UC Davis Center for Healthcare Policy and Research, bill-specific content experts, and information from the bill authors, CHBRP assumes that CGM is not covered in Medi-Cal fee-for-service. Responses to the survey represent 90% of enrollees with private market health insurance that can be subject to state mandates and 57% of Medi-Cal Managed Care (COHS and non-COHS) beneficiaries subject to AB 447.

For further details on the underlying data sources and methods, please see Appendix C

### **Baseline and Postmandate 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 CGM for the treatment and management of diabetes. Conversely, 0% of the 1.5 million beneficiaries in the Medi-Cal fee-for-service program have coverage for CGM 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 CGM for treatment and management of diabetes. AB 447 would codify the requirement to cover CGM for all Medi-Cal beneficiaries, resulting in an added benefit for 9.3% of Medi-Cal managed care beneficiaries and 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. However, because enrollment in FFS Medi-Cal is often a temporary or transitional state, CHBRP deals with the impact on fee-for-service programs separately, as noted below Table 1.

## Baseline and Postmandate Utilization

At baseline, 3.979 CGMs are estimated to be used per 1,000 enrollees 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 CGM 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 (see estimates in Table 1). Although not shown in Table 1, 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. CHBRP is unable to separate spending for real-time or retrospective use of CGMs in the MarketScan claims data used so the two types of CGM are combined in the cost analysis. Also, despite not being able to explicitly estimate discontinuation of CGMs due to the use of claims data (which cannot capture patient discontinuation, misuse, or variation in use of the device), the utilization estimates are based upon actual experience in the commercial market (via MarketScan data), which would include these types of patient behaviors and experiences with CGM.

## Baseline and Postmandate Per-Unit Cost

CHBRP does not estimate that per unit costs in Medi-Cal would change due to AB 447. In the absence of Medi-Cal claims data or managed care fee schedule information, and because price information from Medi-Cal fee-for-service is not available, CHBRP calculated a likely Medi-Cal cost per unit using MarketScan data. Based upon two separate sources on the ratio of commercial, Medicare, and Medicaid fees, CHBRP determined that the cost per unit for CGM would be approximately 46% of the commercial rates seen in MarketScan data (see Appendix C)(Krause et al., 2016; Zuckerman et al., 2014). CHBRP assumes, on average, that rate is already being paid by the managed care plans that cover CGM and the likely cost per unit postmandate would be the same, but more beneficiaries would use CGM and have it covered by their Medi-Cal managed care or COHS plan or the fee-for-service Medi-Cal program. CHBRP estimated that CGMs would cost \$280 per unit, for a total of \$883 annually per user. In addition, \$955 is spent on average for other supplies related to diabetes management. The mandate would not change the estimated unit cost or annual cost per user, but it would increase the number of potential users due to the increase in Medi-Cal enrollees with coverage for CGMs (9.3% in Medi-Cal managed care and COHS, and 100% in fee-for-service).

## Baseline and Postmandate Expenditures

Table 3 and Table 4 present baseline and postmandate expenditures by market segment for DMHC-regulated Medi-Cal managed care plans. The tables present per member per month (PMPM) spending, enrollee expenses for both covered and noncovered benefits, and total expenditures (Medi-Cal spending as well as enrollee out-of-pocket expenses).

AB 447 would increase total net annual expenditures by \$2,105,000 (0.0075% of managed care expenditures) for Medi-Cal managed care plans (see Table 1). 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. CHBRP anticipates that Medi-Cal managed care and COHS plans and the fee-for-service program would use similar prior authorization, utilization review, treatment authorization requests, and provider guidance to cover CGMs when medically necessary. Although COHS are excluded from Table 1 because they are not DMHC-regulated, CHBRP estimated increases in use and expenditures separately. Using the same survey data used for the Medi-Cal managed care population, CHBRP estimated baseline prevalence of potential CGM users and utilization of other diabetes supplies and change postmandate. The state expenditures for Medi-Cal COHS Plans are estimated to increase by \$385,000 due to 9.3% of

the COHS enrollees who would gain coverage for CGM due to AB 447. These impacts assume similarity (in terms of age/sex and disease prevalence, and unit cost) between beneficiaries enrolled in DMHC-plans and beneficiaries enrolled in COHS. As it is not clear how similar the circumstances of the FFS beneficiaries are to the beneficiaries enrolled in DMHC-regulated plans, CHBRP cannot estimate an impact, but presumes there would be an impact for beneficiaries receiving benefits through the FFS program. CHBRP is unable to estimate a percent change in Medi-Cal spending in the FFS program due to lack of detailed information on the budget and overall spending. In addition, because Medi-Cal FFS is often a transitional or temporary state for pending applicants, medically indigent beneficiaries with a share of cost, emergency Medi-Cal beneficiaries, and specific carved-out groups (like California Children's Services beneficiaries), CHBRP cannot accurately predict when beneficiaries would use these services within the year of analysis (2018). It is possible that use would occur after they have transitioned into Medi-Cal managed care plans. Not every FFS group is transitioned into a managed care plan, but the complication of modeling transitions for pending applicants, retroactive claiming processes, carve-outs, and medical exceptions make it difficult to estimate the exact source of the future spending due to the mandate.

## Premiums

Changes in Medi-Cal spending as a result of AB 447 could be concentrated on the fee-for-service program because it does not currently cover CGM at all. Despite new estimated expenditures in the Medi-Cal managed care population, the plans may not receive additional premium payments from the state depending on budget pressures and actuarial estimates. Given that 90.7% of managed care plans already cover CGMs and manage their use and spending through utilization review, provider guidance, and medical necessity determinations, it is possible that the California Department of Health Care Services (DHCS) would not increase the capitated rates paid to managed care plans, despite the additional benefit requirement. Note that such changes are related to the number of enrollees (see Table 1, Table 3 and Table 4), with health insurance that would be subject to AB 447. As Table 1 suggests, among plans that do not cover CGMs, the additional cost in 2018 postmandate would be \$2,105,000 (0.0014% of total expenditures), but it is unclear whether Medi-Cal would raise the capitated rates paid to all plans, or simply expect the plans that did not already cover CGM to absorb the additional costs of covering all required benefits.

## Enrollee Expenses

CHBRP estimates that there would be no AB 447-related changes in enrollee expenses for covered benefits (deductibles, copays, etc.) and enrollee expenses for noncovered benefits for the majority of Medi-Cal beneficiaries. Due to the cost-sharing limits for low-income beneficiaries placed upon Medi-Cal programs, CHBRP does not anticipate beneficiaries would have to pay for any portion of their existing or new CGM use due to AB 447. In addition, because the price paid for CGM in Medi-Cal is likely under the Medicare fee schedule, beneficiaries who are dually eligible for Medi-Cal would not have any additional cost sharing requirements or require Medi-Cal to pay for a portion of their CGM use. Due to Medicare's existing coverage of therapeutic CGMs, the mandate is unlikely to alter the use of CGMs for the dual eligible population.

## Potential Cost Offsets or Savings in the First 12 Months After Enactment

Based upon a comprehensive review of the academic and grey literature, much of which is analyzed in the *Medical Effectiveness* section of this report, CHBRP does not conclude that there would be meaningful cost offsets or savings due to CGM coverage in the first 12 months after enactment. As indicated in the Medical Effectiveness section, while CGM does appear to reduce hypoglycemic and hyperglycemic time for some patients with diabetes, it does not reduce the number of events that would

require additional medical services and spending over a 12-month period (Vazeou, 2011). The literature does indicate that CGM may be effective in controlling diabetes so that it improves birth outcomes for gestational diabetics, including prematurity, complications, and large babies. However, the limited evidence available on the impact of CGMs on birth outcomes suggests that they do not decrease the rate of caesarean sections, although they may reduce the rate of first-time C-section for first-time mothers (Kestila et al., 2007; Yu et al., 2014). In addition, there is insufficient information on cost savings due to improved birth outcomes, if they exist.

CHBRP also gathered information on other services that may be complementary to CGM use, including office visits and other monitoring methods like lancets and test strips that are often used to measure blood sugar. The use of CGM does not eliminate the need for those additional diabetes monitoring supplies and services, due in part to the need to calibrate the CGM device to confirm that CGM readings are accurate. There are specific, newer CGM devices that can reduce the number of finger sticks and supplies needed by patients, but even those CGMs do not eliminate the need for other services or supplies. Because of the need to continue regular monitoring methods, in addition to the use of CGM, CHBRP does not predict any savings due to substitution of CGM for other services, devices, or supplies. In some cases, increased monitoring of blood glucose levels due to CGM would result in early and more frequent treatment with insulin or other non-CGM services. Because CHBRP used commercial claims for patients with DM using CGM to estimate increases in utilization and spending for newly covered Medi-Cal enrollees, the estimates include changes in service use that are related to CGM. If additional training, education, and assistance related to CGM use occurs in the commercial market claims used to estimate utilization and expenditure changes, CHBRP assumed these additional support services would occur in the Medi-Cal population as well.

### **Postmandate Administrative Expenses and Other Expenses**

CHBRP estimates that the increase in administrative costs of DMHC-regulated Medi-Cal managed care plans, COHS and the Medi-Cal fee-for-service program are proportional to the increase in expenditures. CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs. All health plans and insurers include a component for administration and profit (in the case of for-profit Medi-Cal managed care plan contractors) in their premiums or overall expenditures. In the case of Medi-Cal managed care plans, it is unclear if DHCS would pay a higher rate to managed care plans due to the mandate or if they would require the plans with no baseline coverage to absorb the additional 0.0075% in estimated spending postmandate. If the former, the administrative costs would not change. Any change in coverage in fee-for-service Medi-Cal would not result in higher administrative costs for DMHC, but would result in a marginal increase in claims, processing, and treatment authorizations in Medi-Cal fee-for-services that are likely to have administrative costs attached to them.

### **Other Considerations for Policymakers**

In addition to the impacts a bill may have on benefit coverage, utilization, and cost, related considerations for policymakers are discussed below.



### **Postmandate Changes in the number of uninsured persons<sup>13</sup>**

As there is no change in average premiums in the commercial market due to existing coverage for CGM, CHBRP would expect no change in the number of uninsured persons due to the enactment of AB 447.

### **Changes in public program enrollment**

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of AB 447.

### **How Lack of Benefit Coverage Results in Cost Shifts to Other Payers**

At baseline, there is no coverage for CGM in the fee-for-service Medi-Cal program and a 9.3% segment of Medi-Cal Managed Care Plans without coverage. It is unlikely that beneficiaries denied access to CGM would seek care from other payers, instead they are likely to rely on the current standard of care for self-monitoring of blood glucose (SMBG) instead of CGM. For low-income beneficiaries in Medicaid who are dually eligible for Medicare (i.e., dual eligibles), Medicare currently covers the use of therapeutic CGMs and the fee schedule is designed in a way that is unlikely to require Medi-Cal to cover any cost sharing or portion of the Medicare cost.

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<sup>13</sup> See also CHBRP's *Criteria and Methods for Estimating the Impact of Mandates on the Number of Uninsured*, available at [www.chbrp.org/analysis\\_methodology/cost\\_impact\\_analysis.php](http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php).

**Table 3.** Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2018

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) <sup>(a)</sup>			Publicly Funded Plans			Privately Funded Plans (by Market) <sup>(a)</sup>			
	Large Group	Small Group	Individual	CalPERS HMOs <sup>(b)</sup>	MCMC (Under 65) <sup>(c)</sup>	MCMC (65+) <sup>(c)</sup>	Large Group	Small Group	Individual	
<b>Enrollee counts</b>										
Total enrollees in plans/policies subject to state Mandates (d)	9,128,000	3,163,000	2,379,000	884,000	7,192,000	644,000	276,000	145,000	237,000	24,048,000
Total enrollees in plans/policies subject to AB 447	0	0	0	0	7,192,000	644,000	0	0	0	7,836,000
<b>Premiums</b>										
Average portion of premium paid by employer	\$456.42	\$324.76	\$0.00	\$460.43	\$257.00	\$751.00	\$527.06	\$433.40	\$0.00	\$97,688,732,000
Average portion of premium paid by employee	\$115.59	\$149.62	\$469.56	\$115.11	\$0.00	\$0.00	\$166.32	\$157.88	\$423.05	\$34,995,304,000
<b>Total premium</b>	<b>\$572.01</b>	<b>\$474.38</b>	<b>\$469.56</b>	<b>\$575.54</b>	<b>\$257.00</b>	<b>\$751.00</b>	<b>\$693.38</b>	<b>\$591.28</b>	<b>\$423.05</b>	<b>\$132,684,037,000</b>
<b>Enrollee expenses</b>										
Enrollee expenses for covered benefits (Deductibles, copays, etc.)	\$44.11	\$103.11	\$126.07	\$31.49	\$0.00	\$0.00	\$115.39	\$166.25	\$75.74	\$13,565,623,000
Enrollee expenses for benefits not covered (e)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0
<b>Total expenditures</b>	<b>\$616.12</b>	<b>\$577.49</b>	<b>\$595.64</b>	<b>\$607.03</b>	<b>\$257.00</b>	<b>\$751.00</b>	<b>\$808.77</b>	<b>\$757.53</b>	<b>\$498.79</b>	<b>\$146,249,660,000</b>

Source: California Health Benefits Review Program, 2017.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, both on Covered California and outside the exchange.

(b) As of September 2016, 57% of CalPERS HMO members were state retirees under age 65, state employees or their dependents. CHBRP assumes the same ratio for 2018.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who also have Medicare coverage. This population does not include enrollees in COHS.

(d) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. In addition, this only includes those expenses that would be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; COHS=County Organized Health Systems; MCMC = Managed Care Medi-Cal

**Table 4.** Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2018

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) <sup>(a)</sup>			Publicly Funded Plans			Privately Funded Plans (by Market) <sup>(a)</sup>			
	Large Group	Small Group	Individual	CalPERS HMOs <sup>(b)</sup>	MCMC (Under 65) <sup>(c)</sup>	MCMC (65+) <sup>(c)</sup>	Large Group	Small Group	Individual	
<b>Enrollee counts</b>										
Total enrollees in plans/policies subject to state mandates <sup>(d)</sup>	9,128,000	3,163,000	2,379,000	884,000	7,192,000	644,000	276,000	145,000	237,000	24,048,000
Total enrollees in plans/policies subject to AB 447	0	0	0	0	7,192,000	644,000	0	0	0	7,836,000
<b>Premiums</b>										
Average portion of premium paid by employer	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0242	\$0.0026	\$0.0000	\$0.0000	\$0.0000	\$2,105,000
Average portion of premium paid by employee	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
Total premium	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0242	\$0.0026	\$0.0000	\$0.0000	\$0.0000	<b>\$2,105,000</b>
<b>Enrollee expenses</b>										
For covered benefits (deductibles, copays, etc.)	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
For noncovered benefits <sup>(e)</sup>	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
<b>Total expenditures</b>	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0242	\$0.0026	\$0.0000	\$0.0000	\$0.0000	<b>\$2,105,000</b>
<b>Percent Change</b>										
Percent change insured premiums	0.0000%	0.0000%	0.0000%	0.0000%	0.0094%	0.0003%	0.0000%	0.0000%	0.0000%	0.0016%
<b>Percent Change total expenditures</b>	0.0000%	0.0000%	0.0000%	0.0000%	0.0094%	0.0003%	0.0000%	0.0000%	0.0000%	0.0014%

Source: California Health Benefits Review Program, 2017.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, inside and outside the exchange.

(b) As of September 2016, 57% of CalPERS HMO members were state retirees under age 65, state employees or their dependents. CHBRP assumes the same ratio for 2018.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.

(e) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. In addition, this only includes those expenses that would be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

*Key:* CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; COHS = County Organized Health Systems; MCMC = Medi-Cal Managed Care.

## PUBLIC HEALTH IMPACTS

The public health impact analysis includes estimated impacts in the short term (within 12 months of implementation) and in the long term (beyond the first 12 months postmandate). This section estimates the short-term impact<sup>14</sup> of AB 447 on controlling hyper- and hypoglycemic events, quality of life issues related to continuous glucose monitor (CGM) use (including harms), potential disparities, and financial burden for persons with diabetes mellitus (DM). See the *Long-Term Impacts* section for discussion of premature death, economic loss, social determinants of health, and CGM impacts on health complications associated with DM.

### Estimated Public Health Outcomes

Clinical practice guidelines regarding CGM use agree that individual readiness for CGMs should be assessed prior to prescribing, and that robust diabetes education, training, and support are required for optimal CGM implementation and ongoing use (ADA, 2017). Studies show that the patients most likely to benefit 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). In addition, as presented in the *Medical Effectiveness* section, CGM adherence is important to achieving and maintaining good control of glucose levels (HbA1c<7%). 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). There is limited, conflicting, or a lack of evidence of CGM effectiveness in the real-time use and retrospective use by patients with type 2 diabetes mellitus (T2DM). Likewise, evidence is limited for retrospective CGM and insufficient for real-time CGM for improving glucose levels or maternal or infant health outcomes for women with gestational diabetes mellitus (GDM).

As presented in the Benefit Coverage, Utilization, and Cost Impacts section, 9.3% of Medi-Cal beneficiaries in managed care and 100% of Medi-Cal Fee-for-Service beneficiaries would gain parity with their Medi-Cal managed care counterparts for CGM coverage were AB 447 codified. CHBRP estimates that 2,255 Medi-Cal beneficiaries with diabetes would become new users of CGMs under AB 447. Of those, 2,048 beneficiaries with T1DM, 203 beneficiaries with T2DM and four beneficiaries with GDM would use CGMs in 2018 (Table 1). CHBRP estimates no corresponding offsets in adjuvant self-monitoring of blood glucose (SMBG) testing costs.

The effectiveness of CGMs is sensitive to and varies by patient characteristics such as age, race, type of diabetes, and whether a CGM is used real-time or retrospectively. The public health conclusions will be generalized to diabetes overall (combining all three types) and CGM use overall (real-time and retrospective) because CHBRP does not have clinical data available to parse separate outcomes for the subgroups within the population subject to AB 447.

In the first year postmandate, of the 2,255 Medi-Cal managed care beneficiaries newly using continuous glucose monitors (CGMs), CHBRP projects that those who use the CGM consistently would see improvements in glycemic control as compared with self-monitoring blood glucose testing.

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<sup>14</sup> CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.



## Patient Satisfaction, Quality of Life, and Side Effects from Continuous Glucose Monitors

When data are available, CHBRP estimates the marginal change in relevant harms or negative effects associated with interventions associated with the proposed mandate. In the case of AB 447, there is no evidence to suggest that an increase in the use of CGMs could result in increased serious morbidity or mortality for patients with uncontrolled diabetes.

However, there is a limited body of literature that provides conflicting evidence regarding patient satisfaction, quality of life, and side effects with CGM use. Most studies were survey-based with sample sizes ranging from 24 to 1,613, with most studies containing less than 200 participants. Additionally, CHBRP found many studies' findings were limited by potential selection bias wherein current CGM users comprised the denominator rather than also including lapsed CGM users. Key outcomes measured consistently included device accuracy, alarm fatigue, quality of life, fear of hypoglycemic events, physical discomfort, CGM data use, and activity levels.

### *Side effects*

Device accuracy: There appear to be distinct differences in perceptions of CGM accuracy between users and lapsed users; current users felt satisfaction with the CGM while ex-users reported distrust with the data or the machine operating reliably (Polansky and Hessler, 2015). Pickup et al. (2015) reported that among 1- to 2-year CGM users, a minority thought the sensor was generally accurate. Some reported CGMs operated inconsistently with sensor failure occurring earlier than recommended 6- to 7-day lifetime, false alarms, and time lag in calibrating blood glucose with the sensor changes. Halford and Harris (2010) found that 50% of T1DM respondents stopped CGM use because it did not “work” up to their expectations.

Alarm fatigue: Multiple studies reported annoyance with false alarms, and intrusiveness of alarms were mentioned as negative aspects of CGM use, even among adherent users of CGMs (Halford and Harris, 2010; Pickup et al., 2015; Rubin and Peyrot, 2009; Wong 2014; Tansey et al., 2011). For example, Tansey et al. (2011) reported about 35% of T1DM adults and children reporting concerns with alarms. Another study by Pickup et al. (2015) reported mixed reviews by parents of their T1DM children's use of CGM; some felt that constant alarms worried the school, but others reported increased confidence and independence in their children and school staff.

Physical discomfort: Skin reaction to the sensor or adhesive used was reported in several studies investigating patient satisfaction. Tsalikian et al. (2011) reported skin irritations as a primary reason for reduced CGM sensor use in toddlers. Pain at insertion site (which is rotated every 6-7 days) and bulkiness of wearing the CGM (perhaps in addition to an insulin pump) were frequently cited by users as negative aspects to the CGM and possible reasons for discontinued use (Alfadhi, 2016; Halford and Harris, 2010; Hirose et al., 2015; Maurus et al., 2013; Tansey et al., 2011.).

### *Patient satisfaction and quality of life*

Quality of life: Rubin and Peyrot (2009) found no difference in health-related quality of life between adult CGM and SMBG users. Likewise, a literature review by Hirose et al. (2012) reported that three multicenter randomized trials showed no difference in quality of life scores between parents of children using CGM and those using conventional (SMBG) treatment. Two of those studies and another with children and adults found that those with better adherence to CGM, had higher satisfaction than those who used it less often (e.g., fewer than 6 days/week); a similar conclusion was found by Tansey et al. (2011) who studied adults, children and parents of children with T1DM. Conflicting results were reported by Pickup et al. (2015) in which a large majority of parents reported

better sleep with their child's use of a CGM to detect glucose highs during the night. Regarding their children's exercise, some parents noted benefits regarding a reduced need for SMBG testing during exercise or sports and better glucose control, but others noted concerns about damaging the CGM during activity.

*Fear of hypoglycemia:* Some studies reported a reduction in the fear of hypoglycemia for patients using CGMs (Glowinska-Olszewska 2013; Tansey et al., 2011) while others reported no change in fear (Beck et al., 2010). Halford and Harris (2010) reported that all CGM users (continuing and lapsed) reported less fear of hypoglycemic events and a 32% reduction in hypoglycemic events requiring family/friend assistance.

*Amount of CGM Data:* CGM users found detailed information useful in controlling glucose levels while lapsed users reported the detail as overwhelming (Joubert and Reznik; Polansky, 2015). In the Pickup et al. (2015) study, although most CGM users reported CGM advantages outweighed its negative aspects, some did report the risk of becoming obsessed with CGM data. The Alfadhi et al. (2016) study on GDM patients also found that 10% of patients found the CGM unacceptable for use, in part due to anxiety related to constant glucose tracking. Tansey et al. (2011) found that 43% to 53% of adults, youths, and parents of youths who used CGMs appreciated the large amount of detailed data that enabled them to self-correct insulin treatment and detect hypoglycemia.

Another key indicator of patient satisfaction with CGMs is discontinuation rates. Specifically, Wong et al. (2014) reported a 41% discontinuation rate among 1,662 T1DM patients within 12 months. Another study reported a 50% discontinuation rate among 150 CGM users with T1DM (Halford and Harris, 2010).

In summary, the primary theme emerging from the literature is that patients with diabetes either like or dislike CGMs. Those users who report high satisfaction with CGMs are more adherent and have better controlled glycemic levels, higher self-efficacy in managing HbA1c, and fewer complaints about adverse events or side effects. Those patients for whom CGMs are burdensome, reported higher rates of distrust of reading accuracy, false alarm fatigue, physical discomfort, and less adherence/less controlled glucose levels.

In the case of AB 447, there is no evidence to suggest that an increase in the use of CGMs could result in increased serious morbidity or mortality for patients with diabetes.

There is conflicting evidence regarding improvement in patient satisfaction and quality of life through CGM use as compared with SMBG tests; some CGM users report better glycemic management, less fear of hypoglycemia, and satisfaction with sensor data and reliability; and others find CGM use burdensome due to increased anxiety with false alarms, sensor malfunction, and physical discomfort.

Despite reported side effects (e.g., skin irritations at insertion site or from adhesive, false system alarms, or bulkiness of CGM) by some CGM users, CHBRP finds that the benefits of CGMs would outweigh the adverse events for those who are able to adequately adhere to CGM.

## Impact on Disparities<sup>15</sup> in CGM Use and Glycemic Control

Insurance benefit mandates that bring all state-regulated plans and policies to parity may change an existing disparity. CHBRP found evidence that there are racial/ethnic and income disparities in poorly-controlled glucose levels, and some evidence of racial/ethnic disparities in use of CGMs.

### Impact on Income Disparities among Persons with Diabetes

AB 447 focuses exclusively on Medi-Cal, which provides insurance coverage for low-income Californians. CGMs are expensive, with an average retail cost of \$4,000 to \$5,000 and are more likely to be used by those with higher education level, higher household income, and private insurance (Wong et al., 2014). Several studies showed that costs associated with CGM purchase and sensor replacements are reasons for discontinuation (Halford and Harris, 2010; Marian et al., 2017), thus making it more difficult for a low-income population to access and continually use this technology. Furthermore, CHBRP found evidence that Medi-Cal beneficiaries exhibit more difficulty controlling blood glucose levels than their privately insured counterparts. For example, according to the Californian Health Interview Survey, about 52% of Medi-Cal beneficiaries with diabetes were “very confident” in controlling their diabetes, whereas 66% of those with private or employment-based insurance were “very confident” (CHIS, 2017e). Furthermore, the rates of California enrollees with poorly controlled glucose (HbA1c)<sup>16</sup> differ between Medi-Cal managed care beneficiaries and commercial HMO enrollees, at 39% and 27%, respectively (DHCS, 2016; California Right Care Initiative, 2015). A larger proportion of Medi-Cal beneficiaries have uncontrolled diabetes (and are at a higher risk for diabetes complications such as blindness, neuropathy, kidney disease, and stroke) when compared to the commercially insured population.

In addition to the disparity in glucose control between these two insured populations, CHBRP also learned this disparity extends to CGM coverage. CHBRP carrier survey responses indicate that 100% of the California commercial population with insurance subject to state regulation currently has coverage for CGMs, while 9% of the Medi-Cal managed care population does not. Similarly, the traditional fee-for-service Medicare program covers the twice daily calibration CGM model, while the Medi-Cal fee-for-service program does not.

In the first year postmandate, CHBRP projects AB 447 could reduce statewide disparities in access to CGMs between low-income and middle-to-high income individuals with diabetes by bringing Medi-Cal coverage 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 adequately adhere to the newly covered CGMs.

### Impact on Racial/Ethnic Disparities

There are different diabetes prevalence rates among racial/ethnic groups in California. The California Health Interview Survey shows that Latinos comprise 44% of all Californians diagnosed with diabetes, followed by whites (34%), Asians (12%), African Americans (7%), and other (3%). Furthermore, of those Californians with T1DM, 57% are Latino, 27% are white, 9% African American and 5% Asian, and there is a similar distribution of races and ethnicities for T2DM (CHIS, 2017b).

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<sup>15</sup>For details about CHBRP’s methodological approach to analyzing disparities, see [http://www.chbrp.org/analysis\\_methodology/docs/Estimating\\_Impacts\\_on\\_Racial\\_and\\_Ethnic\\_Disparities\\_FINAL.pdf](http://www.chbrp.org/analysis_methodology/docs/Estimating_Impacts_on_Racial_and_Ethnic_Disparities_FINAL.pdf).

<sup>16</sup> HEDIS measure definition: “Comprehensive Diabetes Care—HbA1c Poor Control (>9%) reports percentage of members 18-75 years of age with diabetes (type 1 and type 2) whose most recent HbA1c test conducted during the measurement year showed a greater than 9% HbA1c level, was missing a result, or if an HbA1c test was not done during the measurement period.” DHCS, 2016.

CHBRP found evidence of racial/ethnic disparities in glycemic management and CGM use. Three studies concurred in their findings of disparities by race in treatment regimens for T1DM. For example, Latinos and African Americans had worse glycemic control than whites whether it was for T1DM or T2DM, (Heisler et al., 2009; Lado et al., 2016; Willi et al., 2014) while white children with T1DM reported more blood glucose measurements per day than black and Hispanic children with T1DM (Lado et al., 2016). Lado et al. note that the difference in monitoring frequency may be due to provider instructions; White and Hispanic children with T1DM were instructed more often than black children to test blood glucose four times per day (91.4%, 92.2% and 77.8%, respectively).

Although Latinos are disproportionately represented in Medi-Cal (55%) as compared with private insurance (29%) (which has full coverage for CGMs) and Latinos disproportionately experience T1DM (57%) more than whites who have the second highest prevalence rate (26.5%), it is unlikely that AB 447 could improve statewide disparities in the management of diabetes in California, due to the marginal impact affecting 2,255 beneficiaries.

CHBRP notes that the proportion of minorities enrolled in Medi-Cal is larger than those enrolled in commercial insurance,<sup>17</sup> and AB 447 would bring the remaining 9% (726,000) of DMHC-regulated Medi-Cal managed care enrollees, as well as the Medi-Cal COHS and fee-for-service beneficiaries, into parity with the privately-insured population. However, the impact of AB 447 on reducing *statewide* disparities in controlling glucose levels and CGM use among racial and ethnic groups is unknown because baseline and follow-up CGM utilization data by race/ethnicity are unavailable.

## Estimated Impact on Financial Burden

When possible, CHBRP estimates the marginal impact of mandates on financial burden, defined as uncovered medical expenses paid by the enrollee as well as out-of-pocket expenses (e.g., deductibles, copayments, and co-insurance). In the case of AB 447, which would affect the low-income, Medi-Cal population exclusively, CHBRP assumes that Medi-Cal-only and dual eligibles were unlikely to purchase CGMs themselves (average retail price around \$5,000 for initial purchase and 1-year supply of sensors) (The Perfectd, 2014). Because Medi-Cal has no cost sharing requirement for beneficiaries enrolled in Medi-Cal-only, CHBRP estimates no impact on financial burden due to AB 447.

CHBRP finds that although AB 447 would modify coverage for Medi-Cal beneficiaries, there would be no impact on cost sharing because Medi-Cal policy waives cost-sharing obligations for its beneficiaries.

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<sup>17</sup> According to CHIS, the racial/ethnic composition of Medi-Cal beneficiaries is 52% Latino, 22% white, 9% African American, 8% Asian, and 4% other as compared with the composition of commercially insured enrollees: 46% white, 29% Latino, 16% Asian, 4% African American, and 4% other.

## LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact<sup>18</sup> of AB 447, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

### Long-Term Utilization and Cost Impacts

#### Utilization Impacts

As noted in the *Medical Effectiveness* and *Public Health Impacts* sections of the report, the use of CGM 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 CGM) over 12 months or shorter periods of time. In addition, insurer approvals of CGM and physician decisions to use CGM to manage patients with diabetes are based on clinical guidance, utilization review, and prior authorization requirements implemented by plans. Postmandate, CHBRP assumes that managed care plans and the fee-for-service Medi-Cal program would continue to use similar methods to limit coverage of CGMs to a specific group of beneficiaries with diabetes. It is important to note that consistently well-managed blood glucose levels are still possible without CGM, and the evidence supports that there are either no or very small clinical differences between patients who monitor blood glucose through CGM or SMBG. For certain types of CGM, the reliance on other supplies (e.g., lancets and test strips) is reduced. However, in other cases the utility of CGM is not reduction in supplies (which are still needed for calibration), but real-time information on hypo- and hyperglycemia and the ability to immediately deliver insulin or take other medications that will result in stable blood sugar and less time in hypo- or hyperglycemia. There is insufficient evidence around long-term CGM use, and CHBRP does not anticipate differences over time that are different from those provided in Table 1 and the previous discussion of utilization impacts.

#### Cost Impacts

Similarly to utilization impacts in the long term, there is no evidence to support long-term cost savings or increases in spending due to CGM coverage. CHBRP does not anticipate changes in use of high-cost services (ER and inpatient use) as a result of CGM use, and because CGM and SMBG are similar in terms of managing blood sugar levels in most cases, long-term cost differences are unlikely despite potential public health impacts.

### Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments) while other interventions may take years to make a measurable impact (e.g., coverage for tobacco cessation or vaccinations). When possible, CHBRP estimates the long-term effects (beyond 12-months postmandate) to the public's health that would be attributable to the mandate, including impacts on social determinants of health, premature death, and economic loss.

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<sup>18</sup> See also CHBRP's *Criteria and Guidelines for the Analysis of Long-Term Impacts on Healthcare Costs and Public Health*, available at [http://www.chbrp.org/analysis\\_methodology/cost\\_impact\\_analysis.php](http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php).



As noted in the *Background on Continuous Glucose Monitors and Diabetes Mellitus* section, DM (type 1 and type 2) is the leading cause of blindness, amputations, and kidney failure and a key contributor to stroke, heart disease, dental disease, nerve damage, and premature death. Additionally, GDM is associated with higher rates of T2DM in the long run. There is also clear evidence that those patients with consistently well-managed glucose levels (<7%) experience a much lower incidence of comorbid outcomes (ADA, 2017). However, CHBRP found no literature evaluating the effectiveness of CGMs on preventing, delaying, or ameliorating these long-term comorbidities and complications.

Because there is a lack of evidence regarding 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. 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 could be prevented, delayed, or ameliorated.

### **Impacts on the Social Determinants of Health<sup>19</sup> and Disparities**

Per statute, CHBRP includes discussion of social determinants of health (SDoH), which include factors outside of the traditional medical care system that influence health status and health outcomes (e.g., income, education, geography). In the case of AB 447, evidence shows that social and environmental barriers to care affect proper self-management of DM. A literature review by Walker et al. (2016) of persons with T2DM found weak evidence correlating poor diabetes outcomes with lower socioeconomic status (SES) and hypothesized that financial distress and educational attainment influenced HbA1c through depressive symptoms. They also reported higher HbA1c levels associated with low literacy, lower trust in health care system, and poor social support. Additionally, those experiencing food insecurity and lower neighborhood SES were more likely to have higher HbA1c levels. Kaplan et al. (2013) reported more barriers to care for Mexican Americans and Vietnamese Americans than non-Hispanic whites with T2DM due to geographic inaccessibility, language barriers, inflexible employment, and lack of transportation.

Although income, educational attainment, health literacy, and physical environment are correlated with poorly managed DM, CHBRP finds that AB 447 would not change or ameliorate these SDoH.

In the long term, the impact of AB 447 on social determinants of health and disparities is unknown due to the lack of evidence that these devices prevent, delay, or ameliorate diabetes-related complications, such as blindness, amputations, or kidney disease.

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<sup>19</sup> CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from Healthy People 2020, 2015; CDC, 2014b). See CHBRP's SDoH white paper for further information: [http://www.chbrp.org/analysis\\_methodology/docs/Incorporating\\_Relevant\\_Social\\_Determinants\\_of\\_Health\\_in\\_CHBRP\\_Analyses\\_Final\\_to\\_WEBSITE\\_033016.pdf](http://www.chbrp.org/analysis_methodology/docs/Incorporating_Relevant_Social_Determinants_of_Health_in_CHBRP_Analyses_Final_to_WEBSITE_033016.pdf).



## Impacts on Premature Death<sup>20</sup> and Economic Loss<sup>21</sup>

Diabetes contributes significantly to premature death and economic loss in California. Hypoglycemia is prevalent in T1DM and contributes to 4 to 10 percent of deaths in T1DM patients. And those with HbA1c at 6.9% or lower had a two-fold increased risk of death from any cause compared with a control group (from too many low glucose events) (van Beers et al., 2015). In addition, DM is the seventh leading cause of death in California, and an overall contributor to premature death (e.g., people with diabetes aged 50 years or older die almost 8 years earlier than those without diabetes) (Conroy et al., 2014). The CDC reports that almost 6,000 Californians with diabetes died prematurely in 2013. Despite the diabetes mortality rate decreasing since 1999 for African Americans and Hispanics, these groups still experience twice the mortality rate as non-Hispanic whites, with Asian/Pacific Islanders remaining stable and American Indian and Alaskan Natives fluctuating over time (Conroy et al., 2014).

As noted in the *Background on Continuous Glucose Monitors and Diabetes Mellitus* section, the CDC estimates that diabetes costs Medi-Cal \$3 billion annually in medical costs. For *all* payers across California, the CDC estimates indirect costs (e.g., absenteeism, presenteeism, household productivity loss, inability to work and premature mortality) are \$30 billion annually (2013 dollars) and direct medical costs are \$20.4 billion (2013 dollars) (CDC, 2016).

In the long term, 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.

The impact of AB 447 on economic loss is unknown due to the lack of evidence regarding long-term health outcomes of CGM use.

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<sup>20</sup> Premature death is often defined as death occurring before the age of 75 years<sup>20</sup> (Cox, 2006). In California, it is estimated that there are nearly 102,000 premature deaths each year, accounting for about 1.9 million years of potential life lost (YPLL) (CDPH, 2011).

<sup>21</sup> Economic loss associated with disease is generally presented in the literature as an estimation of the value of the YPLL in dollar amounts (i.e., valuation of a population's lost years of work over a lifetime). In addition, morbidity associated with the disease or condition of interest can also result in lost productivity by causing a worker to miss days of work due to illness or acting as a caregiver for someone else who is ill.

## APPENDIX A TEXT OF BILL ANALYZED

On February 14, 2017, the California Assembly Committee on Health requested that CHBRP analyze AB 447.

CALIFORNIA LEGISLATURE— 2017–2018 REGULAR SESSION

ASSEMBLY BILL

No. 447

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Introduced by Assembly Member Gray

February 13, 2017

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An act to amend Section 14132 of the Welfare and Institutions Code, relating to Medi-Cal.

### LEGISLATIVE COUNSEL'S DIGEST

AB 447, as introduced, Gray. Medi-Cal: covered benefits: continuous glucose monitors.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services. The Medi-Cal program is, in part, governed by, and funded pursuant to, federal Medicaid Program provisions. Existing law provides for a schedule of covered benefits under the Medi-Cal program.

This bill would, to the extent that federal financial participation is available and any necessary federal approvals have been obtained, add continuous glucose monitors that are medically necessary for the management and treatment of diabetes to the schedule of benefits under the Medi-Cal program.

### DIGEST KEY

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

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### BILL TEXT

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

#### SECTION 1.

Section 14132 of the Welfare and Institutions Code is amended to read:

**14132.** The following is the schedule of benefits under this chapter:

(a) Outpatient services are covered as follows:

Physician, hospital or clinic outpatient, surgical center, respiratory care, optometric, chiropractic, psychology, podiatric, occupational therapy, physical therapy, speech therapy, audiology, acupuncture to the extent federal matching funds are provided for acupuncture, and services of persons rendering treatment by prayer or healing by spiritual means in the practice of any church or religious denomination insofar as these can be encompassed by federal participation under an approved plan, subject to utilization controls.

(b) (1) Inpatient hospital services, including, but not limited to, physician and podiatric services, physical therapy and occupational therapy, are covered subject to utilization controls.

(2) For Medi-Cal fee-for-service beneficiaries, emergency services and care that are necessary for the treatment of an emergency medical condition and medical care directly related to the emergency medical condition. This paragraph shall not be construed to change the obligation of Medi-Cal managed care plans to provide emergency services and care. For the purposes of this paragraph, “emergency services and care” and “emergency medical condition” shall have the same meanings as those terms are defined in Section 1317.1 of the Health and Safety Code.

(c) Nursing facility services, subacute care services, and services provided by any category of intermediate care facility for the developmentally disabled, including podiatry, physician, nurse practitioner services, and prescribed drugs, as described in subdivision (d), are covered subject to utilization controls. Respiratory care, physical therapy, occupational therapy, speech therapy, and audiology services for patients in nursing facilities and any category of intermediate care facility for the developmentally disabled are covered subject to utilization controls.

(d) (1) Purchase of prescribed drugs is covered subject to the Medi-Cal List of Contract Drugs and utilization controls.

(2) Purchase of drugs used to treat erectile dysfunction or any off-label uses of those drugs are covered only to the extent that federal financial participation is available.

(3) (A) To the extent required by federal law, the purchase of outpatient prescribed drugs, for which the prescription is executed by a prescriber in written, nonelectronic form on or after April 1, 2008, is covered only when executed on a tamper resistant prescription form. The implementation of this paragraph shall conform to the guidance issued by the federal Centers for Medicare and Medicaid Services but shall not conflict with state statutes on the characteristics of tamper resistant prescriptions for controlled substances, including Section 11162.1 of the Health and Safety Code. The department shall provide providers and beneficiaries with as much flexibility in implementing these rules as allowed by the federal government. The department shall notify and consult with appropriate stakeholders in implementing, interpreting, or making specific this paragraph.

(B) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may take the actions specified in subparagraph (A) by means of a provider bulletin or notice, policy letter, or other similar instructions without taking regulatory action.

(4) (A) (i) For the purposes of this paragraph, nonlegend has the same meaning as defined in subdivision (a) of Section 14105.45.

- (ii) Nonlegend acetaminophen-containing products, with the exception of children's acetaminophen-containing products, selected by the department are not covered benefits.
- (iii) Nonlegend cough and cold products selected by the department are not covered benefits. This clause shall be implemented on the first day of the first calendar month following 90 days after the effective date of the act that added this clause, or on the first day of the first calendar month following 60 days after the date the department secures all necessary federal approvals to implement this section, whichever is later.
- (iv) Beneficiaries under the Early and Periodic Screening, Diagnosis, and Treatment Program shall be exempt from clauses (ii) and (iii).
- (B) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may take the actions specified in subparagraph (A) by means of a provider bulletin or notice, policy letter, or other similar instruction without taking regulatory action.
- (e) Outpatient dialysis services and home hemodialysis services, including physician services, medical supplies, drugs, and equipment required for dialysis, are covered, subject to utilization controls.
- (f) Anesthesiologist services when provided as part of an outpatient medical procedure, nurse anesthetist services when rendered in an inpatient or outpatient setting under conditions set forth by the director, outpatient laboratory services, and X-ray services are covered, subject to utilization controls. Nothing in this subdivision shall be construed to require prior authorization for anesthesiologist services provided as part of an outpatient medical procedure or for portable X-ray services in a nursing facility or any category of intermediate care facility for the developmentally disabled.
- (g) Blood and blood derivatives are covered.
- (h) (1) Emergency and essential diagnostic and restorative dental services, except for orthodontic, fixed bridgework, and partial dentures that are not necessary for balance of a complete artificial denture, are covered, subject to utilization controls. The utilization controls shall allow emergency and essential diagnostic and restorative dental services and prostheses that are necessary to prevent a significant disability or to replace previously furnished prostheses that are lost or destroyed due to circumstances beyond the beneficiary's control. Notwithstanding the foregoing, the director may by regulation provide for certain fixed artificial dentures necessary for obtaining employment or for medical conditions that preclude the use of removable dental prostheses, and for orthodontic services in cleft palate deformities administered by the department's California Children Services Program.  
(2) For persons 21 years of age or older, the services specified in paragraph (1) shall be provided subject to the following conditions:
  - (A) Periodontal treatment is not a benefit.
  - (B) Endodontic therapy is not a benefit except for vital pulpotomy.
  - (C) Laboratory processed crowns are not a benefit.
  - (D) Removable prosthetics shall be a benefit only for patients as a requirement for employment.
  - (E) The director may, by regulation, provide for the provision of fixed artificial dentures that are necessary for medical conditions that preclude the use of removable dental prostheses.

(F) Notwithstanding the conditions specified in subparagraphs (A) to (E), inclusive, the department may approve services for persons with special medical disorders subject to utilization review.

(3) Paragraph (2) shall become inoperative July 1, 1995.

(i) Medical transportation is covered, subject to utilization controls.

(j) Home health care services are covered, subject to utilization controls.

(k) Prosthetic and orthotic devices and eyeglasses are covered, subject to utilization controls.

Utilization controls shall allow replacement of prosthetic and orthotic devices and eyeglasses necessary because of loss or destruction due to circumstances beyond the beneficiary's control.

Frame styles for eyeglasses replaced pursuant to this subdivision shall not change more than once every two years, unless the department so directs.

Orthopedic and conventional shoes are covered when provided by a prosthetic and orthotic supplier on the prescription of a physician and when at least one of the shoes will be attached to a prosthesis or brace, subject to utilization controls. Modification of stock conventional or orthopedic shoes when medically indicated, is covered subject to utilization controls. When there is a clearly established medical need that cannot be satisfied by the modification of stock conventional or orthopedic shoes, custom-made orthopedic shoes are covered, subject to utilization controls.

Therapeutic shoes and inserts are covered when provided to beneficiaries with a diagnosis of diabetes, subject to utilization controls, to the extent that federal financial participation is available.

(l) Hearing aids are covered, subject to utilization controls. Utilization controls shall allow replacement of hearing aids necessary because of loss or destruction due to circumstances beyond the beneficiary's control.

(m) Durable medical equipment and medical supplies are covered, subject to utilization controls.

The utilization controls shall allow the replacement of durable medical equipment and medical supplies when necessary because of loss or destruction due to circumstances beyond the beneficiary's control. The utilization controls shall allow authorization of durable medical equipment needed to assist a disabled beneficiary in caring for a child for whom the disabled beneficiary is a parent, stepparent, foster parent, or legal guardian, subject to the availability of federal financial participation. The department shall adopt emergency regulations to define and establish criteria for assistive durable medical equipment in accordance with the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

(n) Family planning services are covered, subject to utilization controls. However, for Medi-Cal managed care plans, any utilization controls shall be subject to Section 1367.25 of the Health and Safety Code.

(o) Inpatient intensive rehabilitation hospital services, including respiratory rehabilitation services, in a general acute care hospital are covered, subject to utilization controls, when either of the following criteria are met:

(1) A patient with a permanent disability or severe impairment requires an inpatient intensive rehabilitation hospital program as described in Section 14064 to develop function beyond the limited amount that would occur in the normal course of recovery.

(2) A patient with a chronic or progressive disease requires an inpatient intensive rehabilitation hospital program as described in Section 14064 to maintain the patient's present functional level as long as possible.

(p) (1) Adult day health care is covered in accordance with Chapter 8.7 (commencing with Section 14520).

(2) Commencing 30 days after the effective date of the act that added this paragraph, and notwithstanding the number of days previously approved through a treatment authorization request, adult day health care is covered for a maximum of three days per week.

(3) As provided in accordance with paragraph (4), adult day health care is covered for a maximum of five days per week.

(4) As of the date that the director makes the declaration described in subdivision (g) of Section 14525.1, paragraph (2) shall become inoperative and paragraph (3) shall become operative.

(q) (1) Application of fluoride, or other appropriate fluoride treatment as defined by the department, and other prophylaxis treatment for children 17 years of age and under are covered.

(2) All dental hygiene services provided by a registered dental hygienist, registered dental hygienist in extended functions, and registered dental hygienist in alternative practice licensed pursuant to Sections 1753, 1917, 1918, and 1922 of the Business and Professions Code may be covered as long as they are within the scope of Denti-Cal benefits and they are necessary services provided by a registered dental hygienist, registered dental hygienist in extended functions, or registered dental hygienist in alternative practice.

(r) (1) Paramedic services performed by a city, county, or special district, or pursuant to a contract with a city, county, or special district, and pursuant to a program established under former Article 3 (commencing with Section 1480) of Chapter 2.5 of Division 2 of the Health and Safety Code by a paramedic certified pursuant to that article, and consisting of defibrillation and those services specified in subdivision (3) of former Section 1482 of the article.

(2) All providers enrolled under this subdivision shall satisfy all applicable statutory and regulatory requirements for becoming a Medi-Cal provider.

(3) This subdivision shall be implemented only to the extent funding is available under Section 14106.6.

(s) In-home medical care services are covered when medically appropriate and subject to utilization controls, for beneficiaries who would otherwise require care for an extended period of time in an acute care hospital at a cost higher than in-home medical care services. The director shall have the authority under this section to contract with organizations qualified to provide in-home medical care services to those persons. These services may be provided to patients placed in shared or congregate living arrangements, if a home setting is not medically appropriate or available to the beneficiary. As used in this section, "in-home medical care service" includes utility bills directly attributable to continuous, 24-hour operation of life-sustaining medical equipment, to the extent that federal financial participation is available.

As used in this subdivision, in-home medical care services include, but are not limited to:

(1) Level-of-care and cost-of-care evaluations.

(2) Expenses, directly attributable to home care activities, for materials.

(3) Physician fees for home visits.

(4) Expenses directly attributable to home care activities for shelter and modification to shelter.



- (5) Expenses directly attributable to additional costs of special diets, including tube feeding.
  - (6) Medically related personal services.
  - (7) Home nursing education.
  - (8) Emergency maintenance repair.
  - (9) Home health agency personnel benefits that permit coverage of care during periods when regular personnel are on vacation or using sick leave.
  - (10) All services needed to maintain antiseptic conditions at stoma or shunt sites on the body.
  - (11) Emergency and nonemergency medical transportation.
  - (12) Medical supplies.
  - (13) Medical equipment, including, but not limited to, scales, gurneys, and equipment racks suitable for paralyzed patients.
  - (14) Utility use directly attributable to the requirements of home care activities that are in addition to normal utility use.
  - (15) Special drugs and medications.
  - (16) Home health agency supervision of visiting staff that is medically necessary, but not included in the home health agency rate.
  - (17) Therapy services.
  - (18) Household appliances and household utensil costs directly attributable to home care activities.
  - (19) Modification of medical equipment for home use.
  - (20) Training and orientation for use of life-support systems, including, but not limited to, support of respiratory functions.
  - (21) Respiratory care practitioner services as defined in Sections 3702 and 3703 of the Business and Professions Code, subject to prescription by a physician and surgeon.
- Beneficiaries receiving in-home medical care services are entitled to the full range of services within the Medi-Cal scope of benefits as defined by this section, subject to medical necessity and applicable utilization control. Services provided pursuant to this subdivision, which are not otherwise included in the Medi-Cal schedule of benefits, shall be available only to the extent that federal financial participation for these services is available in accordance with a home- and community-based services waiver.
- (t) Home- and community-based services approved by the United States Department of Health and Human Services are covered to the extent that federal financial participation is available for those services under the state plan or waivers granted in accordance with Section 1315 or 1396n of Title 42 of the United States Code. The director may seek waivers for any or all home- and community-based services approvable under Section 1315 or 1396n of Title 42 of the United States Code. Coverage for those services shall be limited by the terms, conditions, and duration of the federal waivers.
- (u) Comprehensive perinatal services, as provided through an agreement with a health care provider designated in Section 14134.5 and meeting the standards developed by the department pursuant to Section 14134.5, subject to utilization controls.

The department shall seek any federal waivers necessary to implement the provisions of this subdivision. The provisions for which appropriate federal waivers cannot be obtained shall not be implemented. Provisions for which waivers are obtained or for which waivers are not required



shall be implemented notwithstanding any inability to obtain federal waivers for the other provisions. No provision of this subdivision shall be implemented unless matching funds from Subchapter XIX (commencing with Section 1396) of Chapter 7 of Title 42 of the United States Code are available.

(v) Early and periodic screening, diagnosis, and treatment for any individual under 21 years of age is covered, consistent with the requirements of Subchapter XIX (commencing with Section 1396) of Chapter 7 of Title 42 of the United States Code.

(w) Hospice service which is Medicare-certified hospice service is covered, subject to utilization controls. Coverage shall be available only to the extent that no additional net program costs are incurred.

(x) When a claim for treatment provided to a beneficiary includes both services that are authorized and reimbursable under this chapter, and services that are not reimbursable under this chapter that portion of the claim for the treatment and services authorized and reimbursable under this chapter shall be payable.

(y) Home- and community-based services approved by the United States Department of Health and Human Services for beneficiaries with a diagnosis of AIDS or ARC, who require intermediate care or a higher level of care.

Services provided pursuant to a waiver obtained from the Secretary of the United States Department of Health and Human Services pursuant to this subdivision, and which are not otherwise included in the Medi-Cal schedule of benefits, shall be available only to the extent that federal financial participation for these services is available in accordance with the waiver, and subject to the terms, conditions, and duration of the waiver. These services shall be provided to individual beneficiaries in accordance with the client's needs as identified in the plan of care, and subject to medical necessity and applicable utilization control.

The director may under this section contract with organizations qualified to provide, directly or by subcontract, services provided for in this subdivision to eligible beneficiaries. Contracts or agreements entered into pursuant to this division shall not be subject to the Public Contract Code.

(z) Respiratory care when provided in organized health care systems as defined in Section 3701 of the Business and Professions Code, and as an in-home medical service as outlined in subdivision (s).

(aa) (1) There is hereby established in the department, a program to provide comprehensive clinical family planning services to any person who has a family income at or below 200 percent of the federal poverty level, as revised annually, and who is eligible to receive these services pursuant to the waiver identified in paragraph (2). This program shall be known as the Family Planning, Access, Care, and Treatment (Family PACT) Program.

(2) The department shall seek a waiver in accordance with Section 1315 of Title 42 of the United States Code, or a state plan amendment adopted in accordance with Section 1396a(a)(10)(A)(ii)(XXI) of Title 42 of the United States Code, which was added to Section 1396a of Title 42 of the United States Code by Section 2303(a)(2) of the federal Patient Protection and Affordable Care Act (PPACA) (Public Law 111-148), for a program to provide comprehensive clinical family planning services as described in paragraph (8). Under the waiver, the program shall be operated only in accordance with the waiver and the statutes and regulations in paragraph (4) and subject to the terms, conditions, and duration of the waiver. Under the state

plan amendment, which shall replace the waiver and shall be known as the Family PACT successor state plan amendment, the program shall be operated only in accordance with this subdivision and the statutes and regulations in paragraph (4). The state shall use the standards and processes imposed by the state on January 1, 2007, including the application of an eligibility discount factor to the extent required by the federal Centers for Medicare and Medicaid Services, for purposes of determining eligibility as permitted under Section 1396a(a)(10)(A)(ii)(XXI) of Title 42 of the United States Code. To the extent that federal financial participation is available, the program shall continue to conduct education, outreach, enrollment, service delivery, and evaluation services as specified under the waiver. The services shall be provided under the program only if the waiver and, when applicable, the successor state plan amendment are approved by the federal Centers for Medicare and Medicaid Services and only to the extent that federal financial participation is available for the services. Nothing in this section shall prohibit the department from seeking the Family PACT successor state plan amendment during the operation of the waiver.

(3) Solely for the purposes of the waiver or Family PACT successor state plan amendment and notwithstanding any other law, the collection and use of an individual's social security number shall be necessary only to the extent required by federal law.

(4) Sections 14105.3 to 14105.39, inclusive, 14107.11, 24005, and 24013, and any regulations adopted under these statutes shall apply to the program provided for under this subdivision. No other provision of law under the Medi-Cal program or the State-Only Family Planning Program shall apply to the program provided for under this subdivision.

(5) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, without taking regulatory action, the provisions of the waiver after its approval by the federal Centers for Medicare and Medicaid Services and the provisions of this section by means of an all-county letter or similar instruction to providers. Thereafter, the department shall adopt regulations to implement this section and the approved waiver in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. Beginning six months after the effective date of the act adding this subdivision, the department shall provide a status report to the Legislature on a semiannual basis until regulations have been adopted.

(6) In the event that the Department of Finance determines that the program operated under the authority of the waiver described in paragraph (2) or the Family PACT successor state plan amendment is no longer cost effective, this subdivision shall become inoperative on the first day of the first month following the issuance of a 30-day notification of that determination in writing by the Department of Finance to the chairperson in each house that considers appropriations, the chairpersons of the committees, and the appropriate subcommittees in each house that considers the State Budget, and the Chairperson of the Joint Legislative Budget Committee.

(7) If this subdivision ceases to be operative, all persons who have received or are eligible to receive comprehensive clinical family planning services pursuant to the waiver described in paragraph (2) shall receive family planning services under the Medi-Cal program pursuant to subdivision (n) if they are otherwise eligible for Medi-Cal with no share of cost, or shall receive comprehensive clinical family planning services under the program established in Division 24

(commencing with Section 24000) either if they are eligible for Medi-Cal with a share of cost or if they are otherwise eligible under Section 24003.

(8) For purposes of this subdivision, “comprehensive clinical family planning services” means the process of establishing objectives for the number and spacing of children, and selecting the means by which those objectives may be achieved. These means include a broad range of acceptable and effective methods and services to limit or enhance fertility, including contraceptive methods, federal Food and Drug Administration approved contraceptive drugs, devices, and supplies, natural family planning, abstinence methods, and basic, limited fertility management. Comprehensive clinical family planning services include, but are not limited to, preconception counseling, maternal and fetal health counseling, general reproductive health care, including diagnosis and treatment of infections and conditions, including cancer, that threaten reproductive capability, medical family planning treatment and procedures, including supplies and followup, and informational, counseling, and educational services. Comprehensive clinical family planning services shall not include abortion, pregnancy testing solely for the purposes of referral for abortion or services ancillary to abortions, or pregnancy care that is not incident to the diagnosis of pregnancy. Comprehensive clinical family planning services shall be subject to utilization control and include all of the following:

(A) Family planning related services and male and female sterilization. Family planning services for men and women shall include emergency services and services for complications directly related to the contraceptive method, federal Food and Drug Administration approved contraceptive drugs, devices, and supplies, and followup, consultation, and referral services, as indicated, which may require treatment authorization requests.

(B) All United States Department of Agriculture, federal Food and Drug Administration approved contraceptive drugs, devices, and supplies that are in keeping with current standards of practice and from which the individual may choose.

(C) Culturally and linguistically appropriate health education and counseling services, including informed consent, that include all of the following:

(i) Psychosocial and medical aspects of contraception.

(ii) Sexuality.

(iii) Fertility.

(iv) Pregnancy.

(v) Parenthood.

(vi) Infertility.

(vii) Reproductive health care.

(viii) Preconception and nutrition counseling.

(ix) Prevention and treatment of sexually transmitted infection.

(x) Use of contraceptive methods, federal Food and Drug Administration approved contraceptive drugs, devices, and supplies.

(xi) Possible contraceptive consequences and followup.

(xii) Interpersonal communication and negotiation of relationships to assist individuals and couples in effective contraceptive method use and planning families.

(D) A comprehensive health history, updated at the next periodic visit (between 11 and 24 months after initial examination) that includes a complete obstetrical history, gynecological

history, contraceptive history, personal medical history, health risk factors, and family health history, including genetic or hereditary conditions.

(E) A complete physical examination on initial and subsequent periodic visits.

(F) Services, drugs, devices, and supplies deemed by the federal Centers for Medicare and Medicaid Services to be appropriate for inclusion in the program.

(9) In order to maximize the availability of federal financial participation under this subdivision, the director shall have the discretion to implement the Family PACT successor state plan amendment retroactively to July 1, 2010.

(ab) (1) Purchase of prescribed enteral nutrition products is covered, subject to the Medi-Cal list of enteral nutrition products and utilization controls.

(2) Purchase of enteral nutrition products is limited to those products to be administered through a feeding tube, including, but not limited to, a gastric, nasogastric, or jejunostomy tube. Beneficiaries under the Early and Periodic Screening, Diagnosis, and Treatment Program shall be exempt from this paragraph.

(3) Notwithstanding paragraph (2), the department may deem an enteral nutrition product, not administered through a feeding tube, including, but not limited to, a gastric, nasogastric, or jejunostomy tube, a benefit for patients with diagnoses, including, but not limited to, malabsorption and inborn errors of metabolism, if the product has been shown to be neither investigational nor experimental when used as part of a therapeutic regimen to prevent serious disability or death.

(4) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement the amendments to this subdivision made by the act that added this paragraph by means of all-county letters, provider bulletins, or similar instructions, without taking regulatory action.

(5) The amendments made to this subdivision by the act that added this paragraph shall be implemented June 1, 2011, or on the first day of the first calendar month following 60 days after the date the department secures all necessary federal approvals to implement this section, whichever is later.

(ac) Diabetic testing supplies are covered when provided by a pharmacy, subject to utilization controls.

(ad) (1) Nonmedical transportation is covered, subject to utilization controls and permissible time and distance standards, for a beneficiary to obtain covered Medi-Cal services.

(2) (A) (i) Nonmedical transportation includes, at a minimum, round trip transportation for a beneficiary to obtain covered Medi-Cal services by passenger car, taxicab, or any other form of public or private conveyance, and mileage reimbursement when conveyance is in a private vehicle arranged by the beneficiary and not through a transportation broker, bus passes, taxi vouchers, or train tickets.

(ii) Nonmedical transportation does not include the transportation of sick, injured, invalid, convalescent, infirm, or otherwise incapacitated beneficiaries by ambulances, litter vans, or wheelchair vans licensed, operated, and equipped in accordance with state and local statutes, ordinances, or regulations.

(B) Nonmedical transportation shall be provided for a beneficiary who can attest in a manner to be specified by the department that other currently available resources have been reasonably

exhausted. For beneficiaries enrolled in a managed care plan, nonmedical transportation shall be provided by the beneficiary's managed care plan. For Medi-Cal fee-for-service beneficiaries, the department shall provide nonmedical transportation when those services are not available to the beneficiary under Sections 14132.44 and 14132.47.

(3) Nonmedical transportation shall be provided in a form and manner that is accessible, in terms of physical and geographic accessibility, for the beneficiary and consistent with applicable state and federal disability rights laws.

(4) It is the intent of the Legislature in enacting this subdivision to affirm the requirement under Section 431.53 of Title 42 of the Code of Federal Regulations, in which the department is required to provide necessary transportation, including nonmedical transportation, for recipients to and from covered services. This subdivision shall not be interpreted to add a new benefit to the Medi-Cal program.

(5) The department shall seek any federal approvals that may be required to implement this subdivision, including, but not limited to, approval of revisions to the existing state plan that the department determines are necessary to implement this subdivision.

(6) This subdivision shall be implemented only to the extent that federal financial participation is available and not otherwise jeopardized, and any necessary federal approvals have been obtained.

(7) Prior to the effective date of any necessary federal approvals, nonmedical transportation was not a Medi-Cal managed care benefit with the exception of when provided as an Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) service.

(8) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department, without taking any further regulatory action, shall implement, interpret, or make specific this subdivision by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions until the time regulations are adopted. By July 1, 2018, the department shall adopt regulations in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. Commencing January 1, 2018, and notwithstanding Section 10231.5 of the Government Code, the department shall provide a status report to the Legislature on a semiannual basis, in compliance with Section 9795 of the Government Code, until regulations have been adopted.

(9) This subdivision shall not be implemented until July 1, 2017.

*(ae) (1) Continuous glucose monitors are covered when medically necessary for the management and treatment of type 1 diabetes, type 2 diabetes, and gestational diabetes.*

*(2) This subdivision shall be implemented only to the extent that federal financial participation is available and any necessary federal approvals have been obtained.*



## APPENDIX B LITERATURE REVIEW METHODS

Appendix B describes methods used in the medical effectiveness literature review conducted for this report. A discussion of CHBRP's system for grading evidence, as well as lists of MeSH Terms, publication types, and keywords, follows.

Studies of the use of CGM for T1DM, T2DM, and GDM were identified through searches of PubMed. Websites maintained by the following organizations were also searched: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network.

The medical effectiveness review searched the literature from 2000 to present. Due to the existence of two high-quality systematic reviews (with meta-analyses) conducted by Cochrane (Langendam et al., 2012) and the Agency on Healthcare Research and Quality (AHRQ) (Golden et al., 2012) in 2012 on the use of CGMs compared with SMBG in patients with T1DM, the medical effectiveness search related to T1DM was limited to studies published from 2012 to the present. The AHRQ systematic review also reviewed literature on the use of real-time CGMs compared with SMBG in patients with T2DM; thus, the medical effectiveness search related to real-time CGM and T2DM was limited to studies published from 2012 to present. To CHBRP's knowledge, no systematic reviews have been conducted on GDM, thus the medical effectiveness search related to GDM was broadened from 2000 to 2017.

Reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria.

The literature review returned abstracts for 967 articles, of which 204 were reviewed for inclusion in this report. A total of 23 studies were included in the medical effectiveness review for AB 447.

### Evidence Grading System

In making a "call" for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's *Medical Effectiveness Analysis Research Approach*.<sup>22</sup> To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Statistical significance;
- Direction of effect;
- Size of effect; and
- Generalizability of findings.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an

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<sup>22</sup> Available at: [www.chbrp.org/analysis\\_methodology/docs/medeffect\\_methods\\_detail.pdf](http://www.chbrp.org/analysis_methodology/docs/medeffect_methods_detail.pdf).



intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

- Clear and convincing evidence;
- Preponderance of evidence;
- Limited evidence
- Conflicting evidence; and
- Insufficient evidence.

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

A grade of *conflicting evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

## Search Terms

The search terms used to locate studies relevant to AB 447 were as follows:

*Keywords used to search PubMed, Cochrane Library, Web of Science, EconLit, and other relevant websites*

(Double quotation marks indicates searching by complete phrase. The "\*" character acts as a word truncation operator. [ti], [tiab] indicates restricting search term or phrase to article title, or title and abstract respectively.)

- |                             |                                  |                            |
|-----------------------------|----------------------------------|----------------------------|
| • "benefit cap"             | • "complementary services"       | • "cost analysis"[ti]      |
| • "birth complications"     | • "continuous blood glucose"     | • "cost benefit"           |
| • "birth weight"            | • "continuous blood glucose"[ti] | • "cost benefit"[ti]       |
| • "cardiovascular disease*" | • "continuous glucose"           | • "cost effective"         |
| • "care map"                | • "continuous glucose"[ti]       | • "cost effective"[ti]     |
| • "care maps"               | • "continuous glucose"[ti]       | • "cost effective*"        |
| • "care pathway"            | • "conventional therapy"[ti]     | • "cost effectiveness"     |
| • "care pathways"           | • "conventional"[ti]             | • "cost effectiveness"[ti] |
| • "clinical pathway"        | • "cost analysis"                | • "cost of illness"        |
| • "clinical pathways"       |                                  | • "cost of treatment"      |
|                             |                                  | • "cost of treatment"[ti]  |
|                             |                                  | • "cost offset"            |

- "cost savings"
- "cost sharing"
- "cost utility"
- "cost utility"[ti]
- "critical pathway"
- "critical pathways"
- "economic loss"
- "economic losses"
- "economic\*"
- "emergency department"
- "emergency room"
- "emergency rooms"
- "emergency service"
- "emergency services"
- "end stage renal disease"
- "fetal macrosomia"
- "gestational diabetes"
- "gestational diabetes"[ti]
- "glycemic control"[ti]
- "glycosylated hemoglobin a"
- "heart disease\*"
- "heart disease\*"
- "high birthweight"
- "incremental cost effectiveness ratio"
- "larger birth size"
- "length of stay"
- "length of stay"[mesh]
- "long-term impact"
- "long-term impacts"
- "long-term outcome"
- "long-term outcomes"
- "low birthweight"
- "out-of-pocket"
- "pathway program"
- "pathway programs"
- "pathways of care"
- "peripheral neuropath\*"
- "peripheral neuropathy"
- "physician visits"
- "premature birth"
- "premature births"
- "premature death"
- "premature deaths"
- "price elasticity"
- "public health"
- "quality of life"
- "respiratory distress"
- "satisfaction"[ti]
- "self-monitoring"[ti]
- "sexual orientation"
- "social class"
- "social determinant"
- "social determinants"
- "social support"
- "substitute services"
- "test strips"
- "treatment cost"
- "treatment cost"[ti]
- "type 2"[ti]
- "type ii"[ti]
- "unit cost"
- "unit cost"[ti]
- a1c
- a1c[ti]
- acceptance[ti]
- adoption[ti]
- adverse
- adverse NEAR effect\*
- adverse NEAR/3 event\*
- adverse[ti]
- affective
- amputation
- amputation\*
- birth
- birth NEAR/3 dystocia
- birth NEAR/3 respiratory distress
- birth NEAR/3 respiratory distress
- birth[ti]
- blinded
- blinded[tiab]
- blindness
- burden
- cancer N3 pathway\*
- cancer\*
- cgm
- CGM
- cgm[ti]
- cgms
- CGMS
- cgms[ti]
- coinsurance
- coma
- comas
- comorbidit\*
- compare
- compared
- comparing
- comparison
- comparison[ti]
- complementary NEAR/2 service\*
- complications
- complications[ti]
- conventional
- conventional[ti]
- copayment
- co-payment
- cost
- cost NEAR/3 treatment
- cost[ti]
- costs
- costs[ti]
- death
- deaths
- deductible
- diabet\*
- diabetes
- diabetes AND "type 1"
- diabetes AND "type 2"
- diabetes AND "type i"
- diabetes AND "type ii"
- diabetes NEAR/3 "type 1"
- diabetes NEAR/3 "type 2"
- diabetes NEAR/3 pregnancy
- diabetes[ti]
- disparities
- disparities[ti]
- disparity
- disparity[ti]
- doctor
- doctor\* NEAR/3 visit\*
- doctor's
- dystocia
- emergency NEAR/3 department\*

- emergency NEAR/3 room\*
- emergency NEAR/3 service\*
- emotional
- emotional[ti]
- esrd
- ESRD
- ethnic
- ethnic\*
- ethnic[ti]
- ethnicity
- ethnicity[ti]
- eye
- eyes
- fetal
- fetal
- fetal[ti]
- fetus
- gender
- gender[tiab]
- gestational NEAR/3 diabet\*
- gestational NEAR/3 diabetes
- glucose NEAR/2 control
- glycemc NEAR/2 control
- harm
- harm\*
- harm[ti]
- harms
- harms[ti]
- hba1c
- hba1c[ti]
- homosexual\*
- hospitali\*
- hospitalisation
- hospitalised
- hospitalization
- hospitalized
- hypoglycemi\*[ti]
- hypoglycemia
- inpatient\*
- inpatient\*[ti]
- in-patient\*[ti]
- instead
- insurance
- insurance[ti]
- ketoacidosis
- ketoacidosis[ti]
- lesbian\*
- long-term
- long-term NEAR/2 impact\*
- long-term NEAR/2 outcome\*
- long-term NEAR/4 outcome\*
- long-term[ti]
- long-term[tiab]
- macrosomia
- masked
- masked[tiab]
- maternal
- maternal[ti]
- medicaid
- minorities
- mortalit\*
- mortality[ti]
- multimorbidit
- multimorbidit\*
- neoplasm\*
- non-blinded
- office NEAR/3 Visit\*
- office\*
- office\*[ti]
- oncolog\*
- outcome\*
- pathway
- pathways
- patient NEAR/4 satisfaction
- physician NEAR/3 visit\*
- physician\*
- pre-eclampsia
- pregnan\* NEAR/3 diabet\*
- pregnan\* NEAR/3 diabetes
- pregnancy
- pregnancy[ti]
- pregnant
- pregnant[ti]
- premature
- premature NEAR/3 death\*
- premature NEAR/3 mortalit\*
- preterm
- preterm[ti]
- price
- price[ti]
- prices
- prices[ti]
- productivity
- productivity[tiab]
- psychological
- psychological[ti]
- psychosocial[ti]
- qol
- quality-of-life[ti]
- quality-of-life[tiab]
- racial
- racial[ti]
- racist
- real-time
- reduce
- reducing
- reduction
- reimbursement
- respiratory distress
- retrospective
- retrospective[tiab]
- rtcgm
- rt-cgm
- safety[ti]
- satisfaction
- self-monitor\*
- self-monitor\*[tiab]
- self-monitored[ti]
- sexism
- sexuality
- short-term
- short-term[tiab]
- smbg
- smbg[ti]
- smbg[tiab]
- social NEAR/3 determinant\*
- socio-economic
- socioeconomic disadvantage
- socio-economic disadvantage
- stress

- |                              |                   |              |
|------------------------------|-------------------|--------------|
| • substitute NEAR/2 service* | • usage[ti]       | • visit*[ti] |
| • tier*                      | • use             | • visual     |
| • tier[tiab]                 | • utilisation     | • vlbw       |
| • transsexual                | • utilisation[ti] | • vs         |
| • tumor*                     | • utilization     | • vs[ti]     |
| • unblinded                  | • utilization[ti] | • vs[tiab]   |
| • underserved                | • versus          | • well-being |
| • usage                      | • versus[ti]      |              |
|                              | • visit*          |              |

*Medical Subject Headings (MeSH)*

([Majr] indicates increased relevance-weighting of subject term. [NoExp] indicates exclusion of more specific MeSH terms below the general term. [Subheading] indicates a “floating” subheading.)

- |   |   |
|---|---|
| • "Affective Symptoms"[Mesh]                            | • "Diabetes, Gestational/drug therapy"[Mesh]                        |
| • "Birth Weight"[Mesh]                                  | • "Diabetic Ketoacidosis"[Majr]                                     |
| • "Blood Glucose Self-Monitoring/adverse effects"[Majr] | • "economics"[Subheading]   |
| • "Blood Glucose Self-Monitoring/adverse effects"[Mesh] | • "Emergency Service, Hospital"[Mesh]                               |
| • "Blood Glucose Self-Monitoring/instrumentation"[Majr] | • "Emergency Service, Hospital/economics"[Mesh]                     |
| • "Blood Glucose Self-Monitoring/methods"[Majr]         | • "Emergency Service, Hospital/statistics and numerical data"[Mesh] |
| • "Blood Glucose Self-Monitoring/utilization"[Majr]     | • "Emergency Service, Hospital/utilization"[Mesh]                   |
| • "Cardiovascular Diseases"[Majr]                       | • "Ethnic Groups"[Mesh]   |
| • "Comorbidity"[Mesh]                                   | • "Gender Dysphoria"[Mesh]  |
| • "Cost of Illness"[Mesh]                               | • "Gender Identity"[Mesh]   |
| • "Cost Sharing"[Mesh]                                  | • "Global Burden of Disease"[Mesh]                                  |
| • "Costs and Cost Analysis"[Majr]                       | • "Healthcare Disparities"[Mesh]                                    |
| • "Costs and Cost Analysis"[Mesh]                       | • "Hemoglobin A, Glycosylated"[Majr]                                |
| • "Diabetes Complications"[Mesh]                        | • "Hospitalization"[Mesh]   |
| • "Diabetes Complications/prevention and control"[Mesh] | • "Hypoglycemia"[Majr:NoExp]  |
| • "Diabetes Mellitus"[Majr:NoExp]                       | • "Hypoglycemia"[Mesh:NoExp]  |
| • "Diabetes Mellitus"[Mesh:NoExp]                       | • "Infant, Premature"[Mesh]   |
| • "Diabetes Mellitus, Type 1"[Majr]                     | • "Inpatients"[Mesh]  |
| • "Diabetes Mellitus, Type 1"[Mesh]                     | • "Insurance Coverage"[Mesh]  |
| • "Diabetes Mellitus, Type 1/drug therapy"[Majr]        | • "Medicaid"[Mesh]  |
| • "Diabetes Mellitus, Type 2"[Majr]                     | • "Minority Health"[Mesh]   |
| • "Diabetes Mellitus, Type 2/drug therapy"[Majr]        | • "Monitoring, Ambulatory/adverse effects"[Mesh]                    |
| • "Diabetes Mellitus/drug therapy"[Majr:NoExp]          | • "Monitoring, Ambulatory/economics"[Majr:NoExp]                    |
| • "Diabetes, Gestational"[Majr:NoExp]                   | • "Monitoring, Ambulatory/psychology"[Mesh]                         |
| • "Diabetes, Gestational"[Mesh]                         | • "Mortality"[Mesh]   |
|   | • "Mortality, Premature"[Mesh]                                      |
|   | • "Office Visits"[Mesh]   |

- "Outcome Assessment Health Care"[Majr:NoExp]
- "Patient Satisfaction"[Majr]
- "Pregnancy in Diabetics"[Majr]
- "Pregnancy in Diabetics"[Mesh:NoExp]
- "Pregnancy in Diabetics"[Mesh]
- "Premature Birth"[Mesh]
- "Quality of Life"[Majr]
- "Quality of Life"[Mesh]
- "Sexism"[Mesh]
- "Sexual Minorities"[Mesh]
- "Sexuality"[Mesh]
- "Social Class"[Mesh]
- "Social Determinants of Health"[Mesh]
- "Social Support"[Mesh]
- "Socioeconomic Factors"[Mesh]
- "Stress, Psychological"[Mesh:NoExp]
- "Treatment Outcome"[Majr:NoExp]
- "Treatment Outcome"[Mesh]

## APPENDIX C COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as the contracted actuarial firms, PricewaterhouseCoopers (PwC).<sup>23</sup>

Information on the generally used data sources and estimation methods, as well as caveats and assumptions generally applicable to CHBRP's cost impacts analyses are available at CHBRP's website.<sup>24</sup>

This appendix describes any analysis-specific data sources, estimation methods, caveats and assumptions used in preparing this cost impact analysis.

### Analysis Specific Caveats and Assumptions

This subsection discusses the caveats and assumptions relevant to specifically to an analysis of AB 447.

There were two core assumptions mentioned in the *Background on Continuous Glucose Monitors and Diabetes Mellitus* section of the report:

- 1) The estimated use of continuous glucose monitors (CGM) by Medi-Cal beneficiaries in the fee-for-service program or managed care plans (including COHS) that currently do not offer coverage will be equivalent to the use currently exhibited in the commercial insurance market by patients with uncontrolled diabetes (based on MarketScan data analysis).
- 2) CHBRP assumes that clinical guidance, utilization review and prior authorization requirements used currently in the commercial insurance market would be equivalent to the medical necessity requirements that Medi-Cal plans and the fee-for-service program would use in deciding when to cover CGM postmandate. The actual use in the commercial market (via MarketScan) should also reflect these types of requirements being implemented in commercial plans. To predict the Medi-Cal managed care market, CHBRP applied assumptions based on higher rates of diabetes prevalence and severity (i.e., uncontrolled diabetes) from the 2015 California Health Interview Survey and the California Right Start Initiative.

In addition to the main assumptions listed in the *Background on Continuous Glucose Monitors and Diabetes Mellitus* section, the CHBRP cost team used the following detailed assumptions to conduct the cost analysis included in this report:

- Because likely Medi-Cal per-unit costs for CGM are not available through published fee schedules or MarketScan data, CHBRP uses the ratio between commercial prices, Medicare, and Medicaid to calculate an estimated cost per-unit for CGM in Medi-Cal. MarketScan commercial prices were approximately 156% of Medicare in Texas, where the Medicaid fee schedule is 80% to 82% of Medicare (Krause et al., 2016; Zuckerman et al., 2014). Thusly, in Texas CHBRP would calculate that the Medicaid per unit cost is 53% of the commercial rates seen in MarketScan claims. Based on this formula, CHBRP calculated a similar per unit cost for California. CHBRP used the 156% of Medicare benchmark for the commercial prices, but applied

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<sup>23</sup> CHBRP's authorizing statute, available at [www.chbrp.org/docs/authorizing\\_statute.pdf](http://www.chbrp.org/docs/authorizing_statute.pdf), requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

<sup>24</sup> See *2017 Cost Impact Analyses: Data Sources, Caveats, and Assumptions*, available at [www.chbrp.org/analysis\\_methodology/cost\\_impact\\_analysis.php](http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php).



California’s lower Medicare-Medicaid fee ratio of 72% for other services (Zuckerman et al., 2014). Using that ratio, CHBRP assumes that the cost per unit for CGMs in Medi-Cal would be 46% of commercial payment.

- Results from the most recent California Health Interview Survey (CHIS), conducted by the UCLA Center for Health Policy Research, indicates a 95% higher diabetes prevalence among the Medi-Cal population vs. the commercial population for Individual, Small Group and Employer Sponsored Insurance, similar to the MarketScan data.
- Uncontrolled diabetes was 44.4% more likely in the Medi-Cal population with diabetes. Rates of utilization in the commercial MarketScan data were adjusted upward to incorporate the higher prevalence rate for both the condition and the relative severity. See Table 2 for additional detail.
- The California Medi-Cal fee schedule has not increased fees since 2015 (CHBRP’s data period.) Consequently, there is no cost or utilization trend applied.
- Carrier responses indicated that all but one Medi-Cal managed care plan already provide medically necessary CGMs. For Dual Medi-Cal/Medicare eligibles, Medicare is assumed to cover 100% of the cost, as the Medi-Cal fee schedule is set sufficiently below the Medicare fee schedule to result in no additional payment obligation. The population over 65 is calculated to have 98.9% coverage, while the Medi-Cal HMO population under 65 is calculated to have 90% coverage. The 2015 MarketScan commercial data primarily covers the population under age 65, and the data in Table 1 reflects this prior to adjustments described above.

**Bill Analysis-Specific Caveats and Assumptions – MarketScan data**

CHBRP determined enrollees diagnosed with T1DM, T2DM, and GDM using ICD-9 and ICD-10 diagnosis codes in 2015 MarketScan commercial California population data.

**Table 5.** Diagnosis Codes Used in the Analysis of AB 447 to Determine Patients with Diabetes

Type 1 Diabetes		Type 2 Diabetes		Gestational Diabetes	
ICD 9 Diagnosis Codes	ICD 10 Diagnosis Codes	ICD 9 Diagnosis Codes	ICD 10 Diagnosis Codes	ICD 9 Diagnosis Codes	ICD 10 Diagnosis Codes
25001	E100	25000	E110	64880	O240
25003	E101	25002	E111	64881	O241
25011	E102	25010	E112	64882	O242
25013	E103	25012	E113	64883	O243
25021	E104	25020	E114	64884	O244
25023	E105	25022	E115	64885	O245
25031	E106	25030	E116	64886	O246
25033	E107	25032	E117	64887	O247
25041	E108	25040	E118	64888	O248
25043	E109	25042	E119	64889	O249
25051		25050			
25053		25052			

Type 1 Diabetes	Type 2 Diabetes	Gestational Diabetes
25061	25060	
25063	25062	
25071	25070	
25073	25072	
25081	25080	
25083	25082	
25091	25090	
25093	25092	

Source: California Health Benefits Review Program, 2017.

The data were further refined by examining the following HCPC and CPT codes. Separate calculations were made for the cost and utilization of continuous glucose monitors and for other diabetes supplies.

**Table 6.** CPT and HCPC Codes Used in the Analysis of AB 447 to Classify Continuous Glucose Monitoring Devices and Other Diabetes Supplies

CGM Devices	Other Diabetes Supplies	
95250	A4221	A4450
95251	A4230	A4455
A9276	A4231	A6257
A9277	A4232	A6258
A9278	A4233	E0607
A9279	A4234	E0784
S1030	A4235	E2100
S1031	A4236	E2101
	A4245	J1815
	A4247	J1817
	A4253	K0552
	A4255	K0601
	A4256	S1034
	A4258	S1035
	A4259	S1036
	A4364	S1037
	A4365	

Source: California Health Benefits Review Program, 2017.

## APPENDIX D INFORMATION SUBMITTED BY OUTSIDE PARTIES

In accordance with the California Health Benefits Review Program (CHBRP) policy to analyze information submitted by outside parties during the first 2 weeks of the CHBRP review, the following parties chose to submit information.

### **The following information was submitted by Medtronic in February 2017.**

Congroy SM, Lee AK, Pednleton L, Bates JH. *Burden of diabetes in California*. Sacramento, CA: Chronic Disease Control Branch, California Department of Public Health; 2014.

Medtronic. *Background and Evidence Regarding the California Health Benefits Review Program Analysis of AB 447 (Gray)*. Unpublished letter; 2017.

Medtronic. *Internal document: Personal Continuous Glucose Monitors (CGM) International Reimbursement Masterfile*. Unpublished; 2013.

Medtronic. *Medtronic Diabetes: Continuous Glucose Monitoring Systems (CGM)*. Presentation to CHBRP; 2017.

Medtronic. *Summary: American Association of Clinical Endocrinologists Consensus Statement, Continuous Glucose Monitoring*. Unpublished slide deck.

Medtronic. *Value of Continuous Glucose Monitoring*. Unpublished Memo; 2017.

Meng Y, Pickett MC, Babey SH, Davis AC, Goldstein H. Diabetes tied to a third of California hospital stays, driving health care costs higher. *UCLA Center for Health Policy Research*. Los Angeles, CA; 2014.

Research and Analytic Studies Division. *Medi-Cal Monthly Enrollment Fast Facts, September 2016*. California Department of Health Care Services (DHCS); 2017.

Stevens CD, Schriger DL, Raffetto B, et al. Geographic clustering of diabetic lower-extremity amputations in low-income regions of California. *Health Affairs*. 2014; 33(8):1380-1390.

UnitedHealthcare. *Commercial Medical Policy: Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes*. 2017.

### **The following information was submitted by the Endocrine Society in February 2017.**

Peters AL, Ahmann AJ, Battelino T, et al. Diabetes Technology – Continuous subcutaneous insulin infusion therapy and continuous glucose monitoring in adults: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinology & Metabolism*. 2016;101(11):3922-3937.

Submitted information is available upon request. For information on the processes for submitting information to CHBRP for review and consideration please visit: [www.chbrp.org/requests.html](http://www.chbrp.org/requests.html).

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## CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM COMMITTEES AND STAFF

A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing contributors to CHBRP from UC that conduct much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, PricewaterhouseCoopers, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP Faculty Task Force comprises rotating representatives from multiple University of California (UC) campuses. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis.

CHBRP staff coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature.

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CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at [www.chbrp.org](http://www.chbrp.org).

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