California Health Benefits Review Program

Analysis of California Senate Bill 694 Medi-Cal: Self-Measured Blood Pressure Devices and Services

A Report to the 2023–2024 California State Legislature

April 16, 2023



Key Findings Analysis of California Senate Bill 694 Medi-Cal: Self-Measured Blood Pressure Devices and Services



Summary to the 2023–2024 California State Legislature, April 16, 2023

AT A GLANCE

For Medi-Cal beneficiaries, the version of California Senate Bill (SB) 694 analyzed by the California Health Benefits Review Program (CHBRP) would require coverage for self-measured blood pressure (SMBP) devices (monitors and cuffs) and two device-related services for the treatment of hypertension. In 2024, approximately 11 million Medi-Cal beneficiaries would have benefit coverage subject to SB 694.

Benefit Coverage: At baseline, 100% of Medi-Cal beneficiaries have coverage for the SMBP devices Postmandate, there would be no change. Postmandate, coverage for education/calibration service would increase for 9% of Medi-Cal beneficiaries. Postmandate, coverage of the 30-day data collection service would increase for 26% of Medi-Cal beneficiaries.

Medical Effectiveness: There is a *preponderance of evidence* that SMBP devices support clinically significant reductions of systolic and diastolic blood pressure (BP) but <u>are not</u> effective at supporting BP control. Evidence is *insufficient* to assess the impact of SMBP devices or the two device-related services on complications of hypertension, quality of life, or use of acute care services. There is *insufficient* evidence to suggest that SMBP devices and the two device-related services are associated with harms.

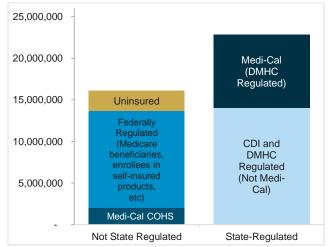
Cost and Health Impacts¹: Device use is expected to remain at approximately 27,080 devices per year (so about 0.2% of Medi-Cal beneficiaries accessing coverage for a device). Use of the education/calibration service and the 30-day data collection services would increase by 110 and 40 uses per year, resulting in a \$2,000 increase in Medi-Cal expenditures. SB 694 would have no measurable short-term public health impact due to a marginal increase in previously low levels of utilization.

BILL SUMMARY

Through reference to specific billing codes, SB 694 would require coverage of self-measured blood pressure (SMBP) devices and coverage of two SMBP device-related services for Medi-Cal beneficiaries for the treatment of hypertension.

- SMBP devices (monitors and cuffs) as defined by two Healthcare Common Procedure Coding System (HCPCS) codes:
 - o A4670 automatic blood pressure monitor
 - A4663 blood pressure cuff
- Two SMBP device-related services as defined by two Current Procedural Terminology (CPT) codes:
 - 99473 education/calibration: patient training and device calibration (billing allowed once per device)
 - 99474 30-day data collection: separate self-measurements of two readings 1 minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver (billing allowed once per calendar month)

Figure A. Health Insurance in CA



and other aspects of health make stability of impacts less certain as time goes by.

¹ Similar cost and health impacts could be expected for the following year, though possible changes in medical science



Source: California Health Benefits Review Program, 2023.

ANATLYTIC APPROACH

As SB 694 addresses coverage for treatment (not diagnosis), this analysis addresses coverage and utilization of SMBP devices and the two device-related services for treatment (not diagnosis) of hypertension.

Although there are other SMBP devices and other device-related services, this analysis addresses only those devices and services indicated by the HCPCS and CPT codes referenced in SB 694.

CONTEXT

Hypertension, also known as high blood pressure, is a significant contributor to numerous conditions such as heart failure, heart attack, stroke, kidney disease/failure, sexual dysfunction, vision loss, and complications in pregnancy (e.g., pre-eclampsia, eclampsia). This preventable and treatable condition contributes to more than 500,000 premature deaths annually in the United States. Controlling blood pressure (BP) is important to preventing such conditions and associated premature death. An estimated 25% of adults diagnosed with hypertension successfully manage it through lifestyle changes and/or medications; the remainder experience uncontrolled hypertension placing them at higher risk of comorbidities and premature death.

Twenty-six percent of adult Californians are diagnosed with hypertension and rates increase as people age. Medi-Cal beneficiaries report consistently higher rates of hypertension than those with other types of insurance.

IMPACTS

Medical Effectiveness

A preponderance of evidence suggests that, relative to usual care, SMBP devices are effective at supporting clinically significant reductions of systolic and diastolic BP but are not effective at supporting BP control (defined as achieving a BP level below a threshold identified by the patient's provider or by study coordinators). There is *insufficient evidence* to assess the direct impact of SMBP devices on complications of hypertension, quality of life, or use of acute care services, although they are associated with reduction in BP, which can reduce the risk that a person with hypertension will develop complications or need acute care services. There is *insufficient evidence* to assess the impact of the two device-related services required by SB 694 (i.e., education/calibration and 30-day data collection) on BP values, BP control, complications of hypertension, quality of life, or use of acute care services. Appendix C discusses other SMBP device-related services that exceed those for which SB 694 would require coverage (e.g., telemonitoring).

There is *insufficient evidence* to suggest that SMBP devices and SMBP device-related services are associated with harms, such as patients adjusting their medication based on their BP measurements without consulting their provider, which might negatively affect control of their hypertension.

Benefit Coverage, Utilization, and Cost

Benefit Coverage

At baseline, all Medi-Cal beneficiaries have coverage for SMBP devices (monitors and cuffs). Postmandate, there would be no change in benefit coverage for devices.

At baseline, 91% Medi-Cal beneficiaries have coverage for the SMBP device-related education/calibration service through their DMHC-regulated plan or through their County Organized Health System (COHS). Postmandate, coverage for this device-related service would increase for 9% of Medi-Cal beneficiaries.

At baseline, 74% of Medi-Cal beneficiaries have coverage for the SMBP device-related data collection service through their DMHC-regulated plan or through their County Organized Health System (COHS). Postmandate, coverage for this device-related service would increase for 26% of Medi-Cal beneficiaries.

Unit Costs

Unit costs (the amounts providers can receive for providing the devices and the services) are limited to \$43 for the device, \$14 for the education/calibration service, and \$11 for the 30-day data collection service. SB 694 would not alter unit costs.

Utilization

As SB 694 would make no change in benefit coverage for SMBP devices, no measurable change in utilization would be expected. Use would be expected to remain at approximately 27,080 devices per year (so about 0.2% of Medi-Cal beneficiaries accessing coverage for a device).



Utilization of the education/calibration service would increase from 1,010 to 1,120 uses per year (an 11% increase).

Utilization of the 30-day data collection service would increase from 130 to 170 uses per year (a 31% increase).

Expenditures

Total expenditures by Medi-Cal for enrollment of beneficiaries in managed care would rise from \$36,606,800,000 to \$36,606,802,000, an increase of \$2,000 (0.000005%).

Public Health

SB 694 would have no measurable short-term public health impact due to a marginal increase in previously low levels of utilization.

Long-Term Impacts

Although CHBRP estimates minimal change in utilization in the first year, Medi-Cal beneficiaries with hypertension who receive and use an SMBP device may be better able to lower their blood pressure values. Lower blood pressure (even if not fully controlled) is associated with better cardiovascular outcomes: fewer strokes, less cardiovascular disease, and less kidney failure. Therefore, there is potential for a long term public health impact should awareness of coverage and subsequent utilization expand among Medi-Cal providers and beneficiaries.

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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-related legislation. The state funds CHBRP through an annual assessment on health plans and insurers in California.

An analytic staff based at the University of California, Berkeley, supports a task force of faculty and research staff from multiple University of California campuses 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. 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 <u>www.chbrp.org.</u>

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	Baseline (2024)	Postmandate Year 1 (2024)	Increase/ Decrease	Change Postmandate
Benefit coverage				
Total enrollees with health				
insurance subject to SB 694	10,957,000	10,957,000	0	0.00%
Percentage of enrollees with				
coverage for SMBP devices	100%	100%	0%	0.00%
Percentage of enrollees with				
coverage for education/calibration				
service	91%	100%	9%	10.43%
Percentage of enrollees with				
coverage for 30-day data	740/	1000/	000/	00.000/
collection service	74%	100%	26%	36.03%
Utilization and cost				
Utilization				
SMBP devices	27,080	27,080	-	0.00%
Education/calibration service	1,010	1,120	110	10.89%
30-day data collection service	130	170	40	30.77%
Average unit costs				
SMBP devices	\$43	\$43	\$0	0.00%
Education/calibration service	\$14	\$14	\$0	0.00%
30-day data collection service	\$11	\$11	\$0	0.00%
Expenditures				
Premiums				
Medi-Cal Managed Care Plan				
expenditures (a)	\$36,606,800,000	\$36,606,802,000	\$2,000	0.000005%
Enrollee out-of-pocket expenses				
Cost sharing for covered benefits				
(deductibles, copayments, etc.)	-	-	-	-
Expenses for noncovered benefits				
(b) (c)	-	-	-	-
Total expenditures	\$36,606,800,000	\$36,606,802,000	\$2,000	0.000005%

Table 1. Impacts of SB 694 on Benefit Coverage, Utilization, and Cost, 2024

Source: California Health Benefits Review Program, 2023.

Notes: (a) Includes Medi-Cal beneficiaries enrolled in DMHC-regulated plans, COHS managed plans, and dually eligible Medi-Cal beneficiaries not enrolled in DMHC-regulated plans. CHBRP assumes beneficiaries in COHS managed plans have premiums similar to beneficiaries under age 65 enrolled in DMHC-regulated plans and dually eligible Medi-Cal beneficiaries not in DMHC-regulated plans have premiums similar to beneficiaries aged 65 and over enrolled in DMHC-regulated plans.

(b) Includes only expenses paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. 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.

(c) For covered benefits, such expenses would be eliminated, although enrollees with newly compliant benefit coverage might pay some expenses if benefit coverage is denied (through utilization management review).

Key: CalPERS = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DMHC = Department of Managed Health; COHS = County Operated Health Systems; SMBP = self-measured blood pressure.

POLICY CONTEXT

The California Senate Committee on Health has requested that the California Health Benefits Review Program (CHBRP)² conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 694, Medi-Cal: Self-Measured Blood Pressure Devices and Services.

Through reference to specific billing codes, SB 694 would require coverage of self-measured blood pressure (SMBP) devices and coverage of two device-related services for Medi-Cal beneficiaries for the treatment of hypertension.

- SMBP devices (monitors and cuffs) as defined by two Healthcare Common Procedure Coding System (HCPCS) codes:
 - A4670 automatic blood pressure monitor
 - A4663 blood pressure cuff
- Two SMBP device-related services as defined by two Current Procedural Terminology (CPT) Codes
 - 99473 education/calibration: patient training and device calibration (billing allowed once per device)
 - 99474 30-day data collection: separate self-measurements of two readings 1 minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver (billing allowed once per calendar month)

The full text of SB 694 can be found in Appendix A.

Relevant Populations

If enacted, SB 694 would apply to the Medi-Cal coverage of approximately 10,957,000 beneficiaries (28% of all Californians) in 2024. This represents Californians who will access benefits through Medi-Cal, including beneficiaries enrolled in Department of Managed Health Care (DMHC)-regulated Medi-Cal managed care plans, beneficiaries enrolled in County Organized Health Systems (COHS), and beneficiaries of both the Medi-Cal and the Medicare programs.

Analytic Approach and Key Assumptions

SMBP devices and device-related services can be used for the diagnosis of hypertension or as part of postdiagnosis treatment for hypertension. As SB 694 addresses coverage for treatment (not diagnosis), this analysis addresses coverage and utilization of SMBP devices and the two device-related services for treatment (not diagnosis) of hypertension.

Although there are other SMBP devices and other device-related services, this analysis addresses only those devices and services indicated by the HCPCS and CPT codes referenced in SB 694.

Interaction with Existing State and Federal Requirements

Health benefit mandates may interact and align with the following state and federal mandates or provisions.

² CHBRP's authorizing statute is available at <u>www.chbrp.org/about_chbrp/faqs/index.php</u>.

California Policy Landscape

California law and regulations

As of June 1, 2022, for Medi-Cal beneficiaries SMBP devices are carved out of coverage provided by DMHC-regulated plans and County Organized Health Systems (COHS) and instead covered by the centralized Medi-Cal RX program (DHCS, 2022a).

Similar requirements in other states

A majority of state Medicaid programs cover SMBP devices (as defined by one or both of the HCPCS codes cited in SB 694) and many cover one or both of the services (as defined by the CPT codes cited in SB 694) (AMA, 2022).

Federal Policy Landscape

Similar requirement for health insurance subject only to Federal regulation

Although SMBP devices and related services are not covered for Medicare beneficiaries, dual-eligibles (beneficiaries of both the Medi-Cal program and the Medicare program) may access SMBP devices and SMBP-related services through Medi-Cal.

Affordable Care Act

The Affordable Care Act (ACA) requires nongrandfathered small-group and individual market health insurance — including but not limited to qualified health plans sold in Covered California — to cover 10 specified categories of essential health benefits (EHBs).^{3, 4}

SB 694 would not result in new benefit coverage that exceeds the definition of EHBs in California, for which nongrandfathered small-group and individual market plans and policies must provide coverage, because SB 694 would only affect Medi-Cal, which is not subject to requirements regarding EHBs.

³ Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website: <u>www.chbrp.org/other_publications/index.php</u>.

⁴ Although many provisions of the ACA have been codified in California law, the ACA was established by the federal government, and therefore, CHBRP generally discusses the ACA as a federal law.

BACKGROUND: HYPERTENSION, SELF-MEASURED BLOOD PRESSURE DEVICES, AND SUPPORT SERVICES

As described in the *Policy Context* section, SB 694 would require coverage of self-measured blood pressure (SMBP) devices and coverage of two SMBP device-related services for Medi-Cal beneficiaries for the treatment of hypertension. SB 694 also specifies coverage of two SMBP device-related service CPT codes: 99473 – patient training and device calibration; and CPT code 99474 – data collection and interpretation of self-measured blood pressure data as reported by the patient and/or caregiver (AMA, 2020).

This section defines hypertension, also known as high blood pressure, and the outcomes that result from it; presents the prevalence of hypertension; and describes disparities associated with the condition. It also describes the SMBP devices, support services, and clinical practice guidelines that inform the use of SMBP monitoring for hypertension.

Hypertension and Its Effects

Hypertension occurs when the pressure against artery walls exerted by blood flow is too high and forces the heart and vessels to work harder (AHA, 2023a). These changes increase the incidence of cardiovascular disease and risk for heart attack, stroke, and kidney disease, and premature death. The Centers for Disease Control and Prevention report that this preventable and treatable condition contributes to more than 500,000 premature deaths annually (CDC, 2022a). Among people aged 48 to 89 years, the risk of death from stroke and heart disease doubles with every 20 mm Hg systolic or 10 mm Hg diastolic increase (NHLBI, 2004).

Controlling blood pressure is important to preventing numerous conditions such as heart failure, heart attack, stroke, kidney disease/failure, sexual dysfunction, vision loss, and complications in pregnancy (e.g., pre-eclampsia, eclampsia) (AHA, 2023b). An estimated 25% of adults diagnosed with hypertension successfully manage it through lifestyle changes and/or medications (CDC, 2022a) the remainder experience uncontrolled hypertension placing them at higher risk of comorbidities and premature death.

Blood pressure is usually measured in a clinical setting using a blood pressure cuff.⁵ The top number is called the systolic blood pressure (SBP) and the bottom number is called the diastolic blood pressure (DBP). Normal blood pressure readings are lower than 120/80.

Table 2 describes the category levels of blood pressure readings. Blood pressure fluctuates throughout the day according to levels of activity, stress, and other factors. Clinicians commonly follow the American College of Cardiology and American Heart Association clinical practice guidelines, which recommend several readings of 130/80 mm Hg or higher before diagnosing a patient with hypertension.

Blood Pressure Terms

Systolic blood pressure (first number): how much pressure blood flow exerts against the artery walls *when your heart beats*.

Diastolic blood pressure (second number): how much pressure blood flow exerts against the artery walls *in between heart beats.*

⁵ Another type of blood pressure measurement is called ambulatory blood pressure monitoring, which occurs over a 24-hour period. Readings are taken intermittently while asleep and as the patient goes about normal daily activities. Readings are analyzed by a clinician who will prescribe a treatment based on the results. https://my.clevelandclinic.org/health/diagnostics/16330-24-hour-ambulatory-blood-pressure-monitoring

Table 2. Blood Pressure Ranges

Blood Pressure Category	Systolic mm Hg (first number)		Diastolic mm Hg (second number)
Low ^a	Less than 90	and	Less than 60
Normal	Less than 120	and	Less than 80
Elevated	120–129	and	Less than 80
Hypertension (stage 1)	130–139	or	80–89
Hypertension (stage 2)	140 or higher		90 or higher
Acute Severe Hypertension (Hypertensive Crisis)	>180	and/or	Higher than 120

Source: California Health Benefits Review Program, 2023, based on AHA, 2023b.

^a Hypotension (low blood pressure) is usually attributed to an underlying health condition or to medication prescribed to treat other health conditions, including high blood pressure. Its prevalence increases with age. Treatment focuses on treating underlying health conditions and hydration (NHLBI, 2022).

Table 3 describes different types of hypertension; patients may be diagnosed with more than one type.

Type of Hypertension	Definition
Essential (or Primary) hypertension	Unknown cause of high blood pressure; majority of hypertensive patients are in this category.
Secondary hypertension	Identifiable cause of hypertension such as adrenal gland or kidney disease, obstructive sleep apnea, thyroid abnormalities, or gestational hypertension. It affects about 5-10% of patients with hypertension, more often in younger people (~30% of those aged 18-40 years with hypertension). In some cases, it can be reversable if the underlying condition is controlled or cured.
White coat hypertension	A temporary increase in blood pressure occurs when some patients are in stressful situations such as visiting the doctor. Clinicians will want to take multiple readings outside of the clinic setting before recommending treatment. Misdiagnosed white coat hypertension could lead to overprescribing medications.
Masked hypertension	Blood pressure is normal when measured in the clinic, but increases outside of the clinic (with readings of at least 135/85 mmHg) indicating primary or secondary hypertension. Estimated prevalence could be up to 30% with diagnosed hypertension.
Gestational hypertension	Occurs in about 5% of pregnant people in California. If not treated, it can lead to maternal and infant mortality and morbidity into the postpartum period.
Resistant hypertension	Essential hypertension that does not respond to treatment, perhaps because a secondary cause is undetected. It affects ~10% of patients with hypertension.
Malignant hypertension or acute severe hypertension (with or without symptoms)	An emergent condition that causes organ damage quickly if not treated quickly (BP >180 mm Hg systolic or >120-130 mm Hg diastolic). It is rare, affecting ~2/100,000 patients with hypertension. This can develop in patients with essential hypertension or in persons with no history of hypertension.

Table 3. Types of Hypertension

Source: California Health Benefits Review Program, 2023, based on Butwick et al., 2020; Franklin et al., 2014; Kivi and Marcin, 2018; Peixoto, 2019; Shimbo et al., 2020.

Prevalence of Hypertension in the California and Medi-Cal Populations

Twenty-six percent of adult Californians are diagnosed with hypertension; rates increase as people age (USHHS, 2020). Medi-Cal beneficiaries report consistently higher rates of hypertension than others. **Error! Not a valid bookmark self-reference.** compares the prevalence of hypertension among Californians with Medi-Cal coverage (subject to SB 694) with those who have insurance from other sources (e.g., private insurance, Medicare) or are uninsured. See the Disparities section below for more discussion.

Demographic Category	Percent of Medi-Cal Adults Reporting Hypertension	Percent of California Adults Not Covered by Medi-Cal Reporting Hypertension
Age in years		
18 – 24	7%	5%
25 – 39	14%	10%
40 - 64	38%	27%
65 – 79	65%	50%
80+	66%	62%
Gender		
Male	32%	26%
Female	28%	26%
Race/Ethnicity		
Asian	31%	19%
Black	44%	38%
Latino	26%	24%
American-Indian/Alaska Native	*	33%
Native Hawaiian/Pacific Islander	*	*
Two or More Races	26%	21%
White	33%	28%

Table 4. Percent of Population Told by a Doctor They Have Hypertension, 2021

Source: California Health Benefits Review Program, 2023 based on CHIS, 2021.

Notes: California adults not covered by Medi-Cal are either uninsured or covered by another insurance source such as private insurance or Medicare.

*The California Health Information Survey (CHIS) reports these categories as statistically unstable.

Pregnant and Postpartum People

An important subpopulation also susceptible to hypertension are pregnant and postpartum people; in this case, hypertension can affect both maternal and neonatal health outcomes. Nationally, California has one of the lowest rates of hypertension during pregnancy — between 6% and 8.6% (Butwick et al., 2020). There are two types of hypertension that can affect pregnant people: gestational hypertension and chronic hypertension. According to the American College of Obstetricians and Gynecologists, diagnosis of gestational hypertension usually occurs after 20 weeks of gestation, with hypertension in the obstetric population defined as systolic blood pressure 140 mm Hg or greater or diastolic blood pressure 90 mm Hg or greater (ACOG, 2020). Chronic hypertension is hypertension that exists before a person becomes pregnant.

Well-managed hypertension during pregnancy can prevent maternal placental abruption, preeclampsia/eclampsia,⁶ and stroke. It can also prevent fetal intrauterine growth restriction and preterm delivery as well as long-term cardiovascular morbidity (CDC, 2023c). Postpartum blood pressure monitoring remains important for managing hypertensive disorders of pregnancy (USPSTF, 2023).

CHBRP notes that Medi-Cal, which is the focus of SB 694, covers approximately 50% (~250,000) of all births in California annually (Simon, 2020).

Hypertension-related Mortality in California

As noted above, uncontrolled hypertension is the primary contributor to stroke, heart attack, and kidney disease. In California, heart disease (1), stroke (6) and hypertension (10) are among the top 10 leading causes of death (CDC, 2023b). In 2020, there were 66,538 (144/100,000) deaths due to heart disease; 17,916 (39/100,000) deaths due to strokes; and 6,086 (13/100,000) deaths due to hypertension (CDC, 2022b; 2022c; 2022d).

Disparities⁷ in Hypertension and Related Conditions

Disparities are noticeable and preventable or modifiable differences between groups of people. Health insurance benefit mandates or related legislation may impact disparities. Where intersections between health insurance benefit mandates and social determinants or systemic factors exist, CHBRP describes relevant literature.

The California Department of Public Health and U.S. Surgeon General report that there are social, economic, and environmental factors that contribute to disparities in rates of hypertension and unmanaged hypertension, which is the primary contributor to cardiovascular disease (CDPH, 2017; USHHS, 2020). Income insecurity, unsafe neighborhoods, and discrimination can lead to stress, a known risk factor for hypertension. These factors can also affect food security/food choices and impede physical activity opportunities, which are also risk factors for uncontrolled hypertension (Khoong et al., 2022). CHBRP found literature identifying some disparities in the prevalence and control of hypertension and related morbidity and mortality by race/ethnicity, education, and income.

Race or Ethnicity

Table 4 demonstrates the disparity between races within Medi-Cal and between non-Medi-Cal and Medi-Cal beneficiaries. In both cases, Black Californians have the highest rates of hypertension among all races/ethnicities. The California Department of Public Health reports that Black Californians' have a 50% higher mortality rate from cardiovascular disease (associated with uncontrolled hypertension) as compared with other Californians. Despite declining rates of cardiovascular mortality overall, death rates among the Black population remain higher than rates among other racial or ethnic populations (USHHS, 2020). Evidence shows that the prevalence of hypertension and cardiovascular disease are persistently higher within the Black population as compared with the White, Latino, and Asian populations (Ostechega et al., 2020; Saeed et al., 2020). Other studies demonstrate that despite equal or greater awareness and treatment of hypertension within the Black population (Ferdinand et al., 2017).

⁶ Placental abruption is the separation of the placental from the uterine wall; preeclampsia is severe medical condition associated with high blood pressure, protein in the urine and other problems that can lead to seizures, known as eclampsia. It may occur during or immediately after pregnancy. It is considered a part of gestational hypertension. ⁷ Several competing definitions of "health disparities" exist. CHBRP relies on the following definition: Health disparity is defined as the differences, whether unjust or not, in health status or outcomes within a population (Wyatt et al., 2016).

Income

The California Department of Public Health (CDPH) also reports that those with lower income experience higher rates of hypertension and cardiovascular disease as compared with people who have family incomes above \$75,000/year (CDPH, 2017).

Controlling Hypertension

Controlling hypertension is essential to preventing the development and/or progression of serious conditions that contribute to higher costs of care and may lead to premature death. In a report by the federal government, the U.S. Surgeon General called the barriers to control significant, citing that 3 of 4 people diagnosed with hypertension have uncontrolled blood pressure (USHHS, 2020).

The report cites various challenges to patients adopting and maintaining healthy lifestyle changes such as low sodium/low fat diets, exercise, low alcohol consumption, smoking cessation, etc.) and adhering to medications.

SMBP devices and device-related services addressed in SB 694 are tools intended to help patients and clinicians identify the proper treatments for controlling blood pressure and to make modifications as necessary. The U.S. Surgeon General recommended SMBP monitoring to engage patients in their care to improve medication adherence and patient-clinician communication (USHHS, 2020).

Self-Measured Blood Pressure (SMBP) Monitoring and Related Services

SMBP Devices

Patients can measure their blood pressure at home using an automated blood pressure monitor with an arm blood pressure cuff (an SMBP device). Although there are manual SMBP devices and wrist cuffs that can be used to measure blood pressure, these devices are not recommended due to the higher risk of error and inaccuracy in blood pressure measurements (although wrist cuffs are an alternative for patients who are unable to use cuffs). CHBRP counted 47 types of SMBP devices covered through Medi-Cal ranging between \$7.39 and \$79.00 maximum allowable cost (DHCS, 2022b). Medi-Cal currently covers the devices at no charge to beneficiaries who receive a prescription from their clinician.

SMBP Device-Related Services and Reimbursement

Figure 1. Example of home blood pressure monitoring device, including the automated (oscillometric) device (left) and upper arm cuff (right) (NIH, 2018)



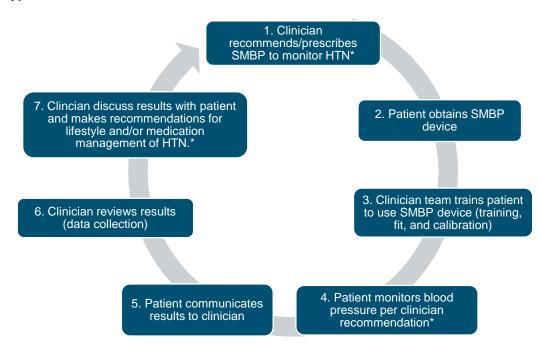
SB 694 also requires coverage of two device-related services:

• Clinicians may be reimbursed (once per device) for patient education and training on the set-up and use of an SMBP device validated for clinical accuracy, including device calibration (CPT code 99473). The arm cuff must be accurately sized to ensure accurate readings.

Clinicians may also be reimbursed for SMBP data collection and interpretation when patients use a BP measurement device validated for clinical accuracy to measure their BP. Data collection is defined as separate patient self-measurements of two readings 1 minute apart, twice daily over a 30-day period (minimum of 12 readings), with data reported by the patient and/or caregiver (billing allowed once per calendar month). The patient must communicate the SMBP measurements back to the practice in person or electronically through secure e-mail, patient portal, or directly from the device (AMA, 2020). Clinicians use the data to form a treatment plan based on the documented average of these readings and communicated to the patient (AMA, 2020).

Figure 2 describes the patient-clinician interaction in the cycle of self-monitoring and managing hypertension. Once patients begin monitoring blood pressure at home, the cycle may be repeated over time to (a) provide the clinician with data for treatment adjustments and (b) support patient engagement in adhering to hypertension treatment to control their hypertension (CDC, 2014). Steps 3, 6 and 7 represent SMBP device-related services specified in SB 694.

Figure 2. Representation of the SMBP Cycle Between Patient and Clinician to Manage Hypertension



Source: California Health Benefits Review Program, 2023, based on CDC, 2014; CPSTF, 2016. *Note:* *After Step 7, the patient may return to Step 4 to continue monitoring the effects of blood pressure management changes. *Key:* HTN = hypertension; SMBP = self-measured blood pressure.

SMBP Clinical Guidelines

International and national guidelines recommend the use of SMBP by patients with hypertension. Nationally, the American Heart Association and American Medical Association recommend that patients be trained to take 2 measurements 1 minute apart in the morning and in the evening for 7 days (28 readings) or at least for 3 days (12 readings) (Shimbo et al., 2020). The Community Preventive Services Task Force recommends use of SMBP to reduce and manage hypertension (CPSTF, 2016). The American College of Obstetricians and Gynecologists recommends home blood pressure monitoring for pregnant people with chronic hypertension (present prior to pregnancy) and poorly controlled blood pressure and weekly home monitoring for pregnant people with gestational hypertension (ACOG, 2013).

Facilitators and Barriers to Patient Use of SMBP

Gathering enough accurate data from the SMBP device for clinicians to make informed treatment recommendations requires patients be trained to use devices that are calibrated. Patients must be motivated to take consistent measurements and report them to their clinician. CHBRP found several studies regarding facilitators and barriers to the effective use of these devices. Most of these studies focused on clinician- and patient-identified barriers that would be mitigated by insurance coverage for SMBP devices and related services, such as cost of SMBP devices, confidence in accurate self-measurement, and proper cuff fit (Borkum et al., 2023; Carter et al., 2018; Gondi et al., 2021). However, these studies also identified several perceived barriers that would remain if insurers covered SMBP devices and/or patient education at no cost to enrollees. Examples include clinician concerns about patient ability to take accurate, consistent measurements; low health literacy levels; and difficulties recording and communicating results using technology (especially for older adults) (Borkum et al., 2023; Carter et al., 2018; Gondi et al., 2021).

Carter et al. (2018) reported that patients appear to have favorable attitudes toward self-measurement of blood pressure overall and that benefits of home measurements outweigh other challenges such as confidence in self-measurement (Carter et al., 2018). Facilitators included patient awareness of white coat hypertension and that accurate readings would prevent unnecessary medication.

Note that hypertension is controlled through adhering to a healthy lifestyle and/or medication. The SMBP device provides information for patients and clinicians to use to monitor the effectiveness of these treatments in controlling blood pressure (see Figure 2).

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, through reference to specific billing codes, SB 694 would require coverage of self-measured blood pressure (SMBP) devices and coverage of two SMBP device-related services for Medi-Cal beneficiaries for the treatment of hypertension.

- SMBP devices (monitors and cuffs) as defined by two Healthcare Common Procedure Coding System (HCPCS) codes:
 - A4670 automatic blood pressure monitor
 - A4663 blood pressure cuff
- Two SMBP device-related services as defined by two Current Procedural Terminology (CPT) codes:
 - 99473 education/calibration: patient training and device calibration (billing allowed once per device)
 - 99474 30-day data collection: separate self-measurements of two readings 1 minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver (billing allowed once per calendar month)

The *Medical Effectiveness* section summarizes findings from literature about SMBP devices and SMBP device-related services published from 2018 to present and from literature reviews conducted by the American Heart Association, the American Medical Association, the Community Preventive Services Task Force, and the U.S. Preventive Services Task Force.

Research Approach and Methods

Studies of SMBP devices and SMBP device-related services were identified through searches of PubMed, the Cochrane Library, Web of Science, Embase, Scopus, and the Cumulative Index of Nursing and Allied Health Literature. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews 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), PubMed Health, the U.S. Preventive Services Task Force, and the Scottish Intercollegiate Guideline Network.

The search was limited to abstracts of studies published in English. The search was limited to studies published from 2018 to present. CHBRP relied on systematic reviews for findings from studies published prior to 2018. Of the 392 articles found in the literature review, 43 were reviewed for potential inclusion in this report on SB 694. A supplementary literature search identified an additional 11 articles that were also reviewed for potential inclusion. A total of 14 studies were included in the medical effectiveness review for this report. The other articles were eliminated because they did not focus on SMBP devices or SMBP device-related services, were experimental or observational studies conducted outside the United States or other developed countries, were of poor quality, or did not report findings from clinical research studies. 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.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.⁸ Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

⁸ Grey literature consists of material that is not published commercially or indexed systematically in bibliographic databases. For more information on CHBRP's use of grey literature, visit <u>https://www.chbrp.org/about/analysis-methodology/medical-effectiveness-analysis</u>.

Key Questions

- 1. Among people with hypertension, do SMBP devices and SMBP device-related services, as compared to usual care,
 - a. Reduce blood pressure (BP) and improve blood pressure control?
 - b. Reduce risk of complications associated with hypertension?
 - c. Reduce use of acute care services?
- 2. Are there harms associated with the use of SMBP devices and SMBP device-related services?

Methodological Considerations

CHBRP identified several important limitations of the literature on SMBP devices and SMBP devicerelated services. First, the SMBP device-related services studied in existing literature are not identical to the services for which SB 694 would require coverage. For example, some studies examined telemonitoring, lifestyle counseling, and/or adherence reminders, but SB 694 does not require health plans to cover such interventions. These studies are included in Appendix C because they do involve some form of patient education, device calibration, and data collection; however, these specific services are not the foci of the interventions studied. Second, some of the individual studies (from 2018 forward) were not randomized controlled trials (RCTs). RCTs are considered the most scientifically rigorous method of hypothesis testing because they maximize the ability to assess whether outcomes are due to an intervention versus other factors (Hariton and Locascio, 2018). Third, few studies assessed the impact of SMBP devices and SMBP device-related services in the long-term. Fourth, many of the meta-analyses noted that there was substantial/considerable heterogeneity between included studies. This is due to variability in factors such as study designs, study populations, measurement devices, and methods of measurement. Lastly, the accuracy of SMBP devices is dependent on whether devices are validated and calibrated⁹. Different populations (e.g., pregnant people) require devices validated specifically for use within that population.

Outcomes Assessed

To assess the impact of SMBP devices and SMBP device-related services on people with hypertension as compared to usual care, CHBRP examined four sets of outcomes.

- Blood pressure values and control of blood pressure
- Complications of hypertension (e.g., heart attack, stroke, kidney disease)
- Quality of life
- Use of acute care services (e.g., emergency department visits, hospitalizations)

The studies included in this CHBRP review defined blood pressure (BP) control as achieving a specific target BP level. Most of the meta-analyses and systematic reviews relied on the target BP levels specified in the included studies to identify persons whose BP was under control. These target levels varied across

⁹ Validated SMBP devices (monitors and cuffs) were submitted by their manufacturers for independent testing and were determined to be clinically accurate. Calibration happens at the individual SMBP device level, where BP measurements taken using the patient's SMBP device are compared with BP measurements taken using the office/clinic's method of BP measurement to assess device accuracy. SB 694 would require coverage of validated SMBP devices and device calibration.

studies; the most frequently cited targets were 140/90 for people who do not have diabetes and 130/80 for people who have diabetes.¹⁰

Study Findings

Several guidelines, scientific statements, and position papers in the United States, including a joint policy statement from the American Heart Association and the American Medical Association (Shimbo et al., 2020) and clinical practice guidelines from the American College of Cardiology and the American Heart Association (Whelton et al., 2017), recommend using SMBP in conjunction with office-based BP monitoring to manage hypertension. As discussed in the *Background* section, office-based BP measurements can be affected by white coat hypertension and masked hypertension. With SMBP, patients are able to measure their BP in between office visits. However, the effectiveness of SMBP as a tool in monitoring BP (and subsequently supporting better BP control) depends on several factors, including adherence (i.e., whether patients actually use the SMBP devices on a consistent basis), patients' ability to use the devices correctly, use of validated devices, proper device calibration, and communication of data back to providers who then use that data to inform treatment decisions.

This following section summarizes CHBRP's findings regarding the strength of evidence for the effectiveness of SMBP devices and SMBP device-related services addressed by SB 694. Each section is accompanied by a corresponding figure. The title of the figure indicates the test, treatment, or service for which evidence is summarized. The statement in the box above the figure presents CHBRP's conclusion regarding the strength of evidence about the effect of a particular test, treatment, or service based on a specific relevant outcome and the number of studies on which CHBRP's conclusion is based. Definitions of CHBRP's grading scale terms is included in the box below, and more information is included in Appendix B.

The following terms are used to characterize the body of evidence regarding an outcome:

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.

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

Limited evidence indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation.

Inconclusive 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.

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.

More information is available in Appendix B.

¹⁰ The target BP levels specified in the included studies to identify persons whose BP was under control varied across studies. Some target BP levels (e.g., <140/90) were notably higher than what is considered normal BP (<120/80). See Table 2 for more information about BP ranges.

SMBP Devices

Impact of use of SMBP devices on blood pressure values and blood pressure control

In 2020, the American Heart Association and the American Medical Association issued a joint policy statement on SMBP, based on evidence gathered from eight meta-analyses published after 2008 that compared the effectiveness of SMBP and SMBP device-related services with usual care (Shimbo et al., 2020).¹¹ Usual care was defined as care that did not include SMBP. The findings regarding the impact of using SMBP devices on BP values and BP control from five of these eight meta-analyses (Agarwal et al., 2011; Glynn et al., 2010; Reboussin et al., 2018; Tucker et al., 2017; Uhlig et al., 2013) are summarized below.¹²

Table 5 presents findings from the five meta-analyses, two individual patient data meta-analyses¹³ (Bryant et al., 2020; Sheppard et al., 2020), and one prospective cohort study (Spirk et al., 2018) that assessed the impact of SMBP devices on BP values and BP control.

Table 5. Summary of Evidence of Medical Effectiveness of Use of SMBP Devices on BloodPressure Values and Blood Pressure Control

	BP V	alues	BP Control		
Study (Research Design)	Result	Finding	Result	Finding	
Glynn et al. (2010) (Meta-analysis of 18 RCTs)	Systolic –2.5 mm Hg reduction (95% Cl: –3.7, –1.3) Diastolic –1.8 mm Hg reduction (95% Cl: –2.4, –1.2)	Statistically significant differences	Improvement in BP control: OR 1.0 (95% CI: 0.8, 1.2)	No statistically significant difference	
Agarwal et al. (2011) (Meta-analysis of 22 RCTs)	Systolic –2.63 mm Hg reduction (95% Cl: –4.24, –1.02) Diastolic –1.68 mm Hg reduction (95% Cl: –2.58, –0.79)	Statistically significant differences	The proportion of study participants who reached their BP target favored SMBP by 11%	No statistically significant difference	
Uhlig et al. (2013) (Meta-analysis of 26 prospective comparative studies)	Separate results by time since start of intervention (2, 3, 6, 12, 18, 24 months)	Statistically significant differences at 3 and 6 months No statistically significant differences at 2 months or beyond 12 months	Not reported	Mixed findings across individual studies	

¹¹ Although these meta-analyses predate the publication period selected for this medical effectiveness analysis (i.e., 2018 to present), CHBRP decided to include these meta-analyses because they were cited in the 2020 American Heart Association and American Medical Association joint policy statement and because they synthesize the most recent findings available on the impact of SMBP on BP values and BP control.

¹² The other three meta-analyses cited in the American Heart Association and the American Medical Association joint policy statement synthesized findings from studies of SMBP device-related services.

¹³ Individual patient data meta-analyses are studies that combine patient-level data from multiple studies to estimate overall effects of interventions. Traditional meta-analyses estimate overall findings based on the mean effects of interventions on the populations studied.

	BP V	alues	BP C	ontrol
Study (Research Design)	Result	Finding	Result	Finding
Tucker et al. (2017) (Meta-analysis of 25 RCTs)	Systolic -1.02 mm Hg reduction (95% Cl: -3.27, 1.23) Diastolic -1.10 mm Hg reduction (95% Cl: -2.39, 0.19)	No statistically significant differences	RR of uncontrolled BP: 1.0 (95% CI: 0.7, 1.4)	No statistically significant difference
Reboussin et al. (2018) (Meta-analysis of 13 RCTs)	Systolic (6 months) 4.9 mm Hg reduction (95% Cl: 1.3, 8.6) Systolic (12 months) 0.1 mm Hg reduction (95% Cl: -2.54, 2.8)	Statistically significant difference in systolic BP at 6 months but not at 12 months	Results from online appendix not available	No statistically significant difference
Spirk et al. (2018) (Prospective cohort study of 1,268 people)	Systolic lowered to 138±13 mm Hg with SMBP and 139±14 without SMBP (p<0.046) Diastolic lowered to 83±9 mm Hg with SMBP and 84±9 mm Hg without SMBP (p=0.41)	Statistically significant difference for systolic BP but not for diastolic BP	% of patients who reached their BP goal: 64% with SMBP vs. 57% without SMBP (p=0.028)	Statistically significant difference
Bryant et al. (2020) (Individual patient data meta-analysis of 4 RCTs)	Systolic −3.8 mm Hg reduction (95% Cl: −5.8, −1.8) Diastolic −1.5 mm Hg reduction (95% Cl: −2.5,−0.4)	Statistically significant differences	5-year BP control rate: 52.4% with SMBP (projected, if participants continued receiving SMBP all 5 years) vs. 33.9% with SMBP (projected, if participants stopped receiving SMBP after 12 months and started receiving usual care) vs. 33.4% with usual care alone	SMBP projected to be higher % controlled if BP process improvements and adherence sustained for 5 years
Sheppard et al. (2020) (Individual patient data meta-analysis of 5 RCTs)	Not reported	Systolic BP not statistically significant in 4 of 5 studies Diastolic BP not statistically significant in 3 of 5 studies	Not reported	Not reported

Source: California Health Benefits Review Program, 2023.

Key: BP = blood pressure; CI = confidence interval; OR = odds ratio; RCT = randomized controlled trial; RR = relative risk; SMBP = self-measured blood pressure.

Blood pressure values

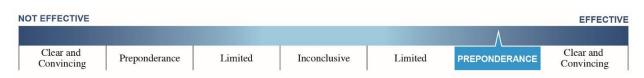
Four of the meta-analyses (Agarwal et al., 2011; Glynn et al., 2010; Reboussin et al., 2018; Uhlig et al., 2013), one of the individual patient data meta-analyses (Bryant et al., 2020), and the prospective cohort study (Spirk et al., 2018) found that use of SMBP devices was associated with a statistically significant reduction in systolic BP relative to usual care at one or more time intervals post intervention. In these meta-analyses, mean decreases in systolic BP ranged from -2.5 mm Hg (Glynn et al., 2010) to -4.9 mm Hg (Reboussin et al., 2018). One individual patient data meta-analysis found no difference in systolic BP (Tucker et al., 2017). One meta-analysis that did not report pooled findings for systolic BP across studies reported that four of the five studies it included did not find a statistically significant difference in BP between people who used SMBP devices and people who received usual care (Sheppard et al., 2020).

In the meta-analyses that reported statistically significant reductions in systolic BP, the reductions were large enough to be clinically significant. According to studies cited by Uhlig et al. (2013), a decrease in systolic BP of 2 to 5 mm Hg in a population has been estimated to reduce the risk of mortality due to stroke by 6 or 14 percent, the risk of mortality due to heart diseases by 4 or 9 percent, and the risk of mortality due to any cause by 3 or 7 percent.

Three of the meta-analyses (Agarwal et al., 2011; Glynn et al., 2010; Uhlig et al., 2013) and one of the individual patient data meta-analyses (Bryant et al., 2020) found that use of SMBP devices was associated with a statistically significant reduction in diastolic BP relative to usual care. In these meta-analyses, mean decreases in diastolic BP ranged from -1.5 mm Hg (Bryant et al., 2020) to -2.4 mm Hg (Uhlig et al., 2013). The prospective cohort study (Spirk et al., 2018) and one of the individual patient data meta-analyses (Tucker et al., 2017) found no statistically significant difference in diastolic BP between people who used SMBP devices and people who received usual care. One meta-analysis that did not report pooled findings for diastolic BP across studies reported that three of the five studies it included did not find a statistically significant difference in BP between people who used SMBP devices and people who received usual Care (Sheppard et al., 2020).

Summary of findings regarding the impact of use of SMBP devices on blood pressure values: There is a *preponderance of evidence* from four meta-analyses, three individual patient data metaanalyses, and one prospective cohort study that use of SMBP devices is associated with statistically significant reductions in systolic and diastolic BP relative to usual care and that reductions in systolic BP are large enough to be clinically significant.

Figure 3. Impact of Use of SMBP Devices on Blood Pressure Values



Blood pressure control

As indicated in the Outcomes Assessed section, the studies included in this CHBRP review defined blood pressure control as achieving a specific target BP level. These target levels varied across studies included in the meta-analyses and systematic reviews; the most frequently cited targets were 140/90 for people who do not have diabetes and 130/80 for people who have diabetes.

Four meta-analyses, two individual patient data meta-analyses, and one prospective cohort study examined the impact of SMBP devices on BP control relative to usual care. Three of the meta-analyses (Agarwal et al., 2011; Glynn et al., 2010; Reboussin et al., 2018) and one individual patient data meta-analysis (Tucker et al., 2017) found no statistically significant difference in the likelihood of attaining BP control between people who used SMBP devices and people who received usual care. The authors of

one meta-analysis reported that use of SMBP devices was associated with statistically significant increases in the likelihood of achieving BP control at 2 or 3 months post intervention but was not associated with a statistically significant difference at 6 or 12 months post intervention (Uhlig et al., 2013). One individual patient data meta-analysis projected that use of SMBP devices would result in a higher percentage of patients attaining BP control if BP monitoring and adherence to treatment regimens were sustained for 5 years (Bryant et al., 2020). The prospective cohort study concluded that people who used SMBP devices were more likely to attain their BP control goals than people who received usual care (Spirk et al., 2018).

Summary of findings regarding the impact of use of SMBP devices on blood pressure control: There is a *preponderance of evidence* from four meta-analyses, two individual patient data metaanalyses, and one prospective cohort study that use of SMBP devices does not increase the likelihood that people will attain BP control (as defined by prespecified thresholds) relative to usual care.

Figure 4. Impact of Use of SMBP Devices on Blood Pressure Control

NOT EFFECTIVE					EFFECTIVE
Clear and Convincing	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing

Impact of use of SMBP devices on complications of hypertension

CHBRP did not identify any studies published within the last 5 years that directly assessed the impact of SMBP devices on complications of hypertension (e.g., heart attack, stroke, kidney disease). Thus, CHBRP concluded that there is *insufficient evidence* on the impact of SMBP devices on complications of hypertension. However, the absence of evidence does not indicate that SMBP has no effect on complications of hypertension. SMBP devices may have an indirect effect on complications of hypertension because their use may be associated with reduction of BP values, which may lower the risk of complications (Shimbo et al., 2020).

Summary of findings regarding the impact of use of SMBP devices on complications of hypertension: There is *insufficient evidence* to assess the direct impact of use of SMBP devices on complications of hypertension.

Figure 5. Impact of Use of SMBP Devices on Complications of Hypertension

NOT EFFECTIVE		EFFECTIVE				
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing

Impact of use of SMBP devices on quality of life

CHBRP did not identify any studies published within the last 5 years that directly assessed the impact of SMBP devices on quality of life. Thus, CHBRP concluded that there is *insufficient evidence* on the impact of SMBP devices on quality of life. However, the absence of evidence does not indicate that SMBP has no effect on quality of life.

Summary of findings regarding the impact of use of SMBP devices on quality of life: There is *insufficient evidence* to assess the direct impact of use of SMBP devices on quality of life.

Figure 6. Impact of Use of SMBP Devices on Quality of Life

NOT EFFECTIVE	i	EFFECTIVE				
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing

Impact of use of SMBP devices on use of acute care services

CHBRP did not identify any studies published within the last 5 years that directly assessed the impact of use of SMBP devices on use of acute care services, such as emergency department visits or inpatient admissions. Thus, CHBRP concluded that there is *insufficient evidence* on the impact of SMBP devices on use of acute care services. However, the absence of evidence does not indicate that SMBP has no effect on acute care use. SMBP devices may have an indirect effect on use of acute care services because their use may be associated with reduction of BP values, which may reduce need for acute care services.

Summary of findings regarding the impact of use of SMBP devices on use of acute care services: There is *insufficient evidence* to assess the direct impact of use of SMBP devices on use of acute care services.

Figure 7. Impact of Use of SMBP Devices on Use of Acute Care Services

NOT EFFECTIVE		EFFECTIVE				
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing

SMBP Device-Related Services

This subsection discusses evidence regarding the specific SMBP device-related services for which SB 694 would require coverage (i.e., education/calibration and 30-day data collection). Appendix C discusses other SMBP device-related services that exceed those for which SB 694 would require coverage (e.g., telemonitoring). These other SMBP device-related services are discussed in Appendix C because while these studies do not focus primarily on education/calibration and/or 30-day data collection, many of them involve some form of patient education, device calibration, and/or data collection.

Impact of use of SMBP device-related services on blood pressure values and blood pressure control

Blood pressure values

CHBRP did not identify any studies published within the last 5 years that assessed the impact of use of the SMBP device-related services for which SB 694 would require coverage on BP values. Thus, CHBRP concluded that there is *insufficient evidence* on the impact of these SMBP device-related services on BP values. However, the absence of evidence does not indicate that these SMBP device-related services have no effect on BP values.

Summary of findings regarding the impact of use of SMBP device-related services for which SB 694 would require coverage on blood pressure values: There is *insufficient evidence* to access the impact of use of SMBP device-related services for which SB 694 would require coverage on blood pressure values.

Figure 8. Impact of Use of SMBP Device-Related Services for Which SB 694 Would Require Coverage on Blood Pressure Values

NOT EFFECTIVE		EFFECTIVE				
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing

Blood pressure control

CHBRP did not identify any studies published within the last 5 years that assessed the impact of use of the SMBP device-related services for which SB 694 would require coverage on BP control. Thus, CHBRP concluded that there is *insufficient evidence* on the impact of these SMBP device-related services on BP control. However, the absence of evidence does not indicate that these SMBP device-related services have no effect on BP control.

Summary of findings regarding the impact of use of SMBP device-related services for which SB 694 would require coverage on blood pressure control: There is *insufficient evidence* to access the impact of use of SMBP device-related services for which SB 694 would require coverage on blood pressure control.

Figure 9. Impact of Use of SMBP Device-Related Services for Which SB 694 Would Require Coverage on Blood Pressure Control

NOT EFFECTIVE		EFFECTIVE				
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing

Impact of use of SMBP device-related services on complications of hypertension

CHBRP did not identify any studies published within the last 5 years that directly assessed the impact of use of the SMBP device-related services for which SB 694 would require coverage on complications of hypertension (e.g., heart attack, stroke, kidney disease). Thus, CHBRP concluded that there is *insufficient evidence* on the impact of these SMBP device-related services on complications of hypertension. However, the absence of evidence does not indicate that these SMBP device-related services have no effect on complications of hypertension.

Summary of findings regarding the impact of use of SMBP device-related services for which SB 694 would require coverage on complications of hypertension: There is *insufficient evidence* to assess the direct impact of use of SMBP device-related services for which SB 694 would require coverage on complications of hypertension.

Figure 10. Impact of Use of SMBP Device-Related Services for Which SB 694 Would Require Coverage on Complications of Hypertension

NOT EFFECTIVE	INSUFFICIENT EVIDENCE					EFFECTIVE
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing

Impact of use of SMBP device-related services on quality of life

CHBRP did not identify any studies published within the last 5 years that directly assessed the impact of the SMBP device-related services for which SB 694 would require coverage on quality of life. Thus, CHBRP concluded that there is *insufficient evidence* on the impact of these SMBP device-related services on quality of life. However, the absence of evidence does not indicate that these SMBP device-related services have no effect on quality of life.

Summary of findings regarding the impact of use of SMBP device-related services for which SB 694 would require coverage on quality of life: There is *insufficient evidence* to assess the direct impact of use of SMBP device-related services for which SB 694 would require coverage on quality of life.

Figure 11. Impact of Use of SMBP Device-Related Services for Which SB 694 Would Require Coverage on Quality of Life

NOT EFFECTIVE		INSUFFICIENT EVIDENCE				
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing

Impact of use of SMBP device-related services on use of acute care services

CHBRP did not identify any studies published within the last 5 years that directly assessed the impact of use of the SMBP device-related services for which SB 694 would require coverage on use of acute care services, such as emergency department visits or inpatient admissions. Thus, CHBRP concluded that there is *insufficient evidence* on the impact of use of these SMBP device-related services on use of acute care services. However, the absence of evidence does not indicate that these SMBP device-related services have no effect on acute care use.

Summary of findings regarding the impact of use of SMBP device-related services for which SB 694 would require coverage on use of acute care services: There is *insufficient evidence* to assess the direct impact of use of SMBP device-related services for which SB 694 would require coverage on the use of acute care services.

Figure 12. Impact of Use of SMBP Device-Related Services for Which SB 694 Would Require Coverage on Use of Acute Care Services

NOT EFFECTIVE		EFFECTIVE				
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing

Harms of SMBP Devices and SMBP Device-Related Services

CHBRP did not identify any studies that identified harms associated with the use of SMBP devices and SMBP device-related services. In a 2016 statement on SMBP, the Community Preventive Services Task Force noted that one potential harm of SMBP devices is that patients might adjust their medication based on their BP measurements without consulting their provider, which might negatively affect control of their hypertension. However, CHBRP did not identify any studies indicating that patients who used SMBP devices were more likely to adjust their medication on their own compared to patients who did not use SMBP devices.

Summary of findings regarding the harms of SMBP devices and SMBP device-related services: There is *insufficient evidence* that SMBP devices and SMBP device-related services are associated with harms.

Summary of Findings

A preponderance of evidence suggests that, relative to usual care, SMBP devices are effective at supporting clinically significant reductions of systolic and diastolic BP but are not effective at supporting BP control (defined as achieving a BP level below a threshold identified by the patient's provider or by study coordinators). There is *insufficient evidence* to assess the direct impact of SMBP devices on complications of hypertension, quality of life, or use of acute care services, although they are associated with reduction in BP, which can reduce the risk that a person with hypertension will develop complications or need acute care services.

There is *insufficient evidence* to assess the impact of the SMBP device-related services required by SB 694 (i.e., education/calibration and 30-day data collection) on BP values, BP control, complications of hypertension, quality of life, or use of acute care services. Appendix C discusses other SMBP device-related services that exceed those for which SB 694 would require coverage (e.g., telemonitoring).

There is *insufficient evidence* that SMBP devices and SMBP device-related services are associated with harms.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, SB 694 would require for Medi-Cal beneficiaries coverage of self-measured blood pressure (SMBP) devices and coverage of two device-related services for treatment of hypertension.

- SMBP devices (monitors and cuffs) as defined by two Healthcare Common Procedure Coding System (HCPCS) Codes:
 - A4670 automatic blood pressure monitor
 - A4663 blood pressure cuff
- Two SMBP device-related services as defined by two Current Procedural Terminology (CPT) Codes:
 - 99473 education/calibration: patient training and device calibration (provider billing allowed once per device)
 - 99474 30-day data collection: separate self-measurements of two readings 1 minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver (provider billing allowed once per calendar month)

The full text of SB 694 can be found in Appendix A.

Analytic Approach and Assumptions

This report's Table 1 provides estimates of both baseline and postmandate benefit coverage for and utilization for the SMBP devices and device-related services addressed by SB 694,.

Baseline coverage for SMBP devices (as defined by the codes cited in SB 694) was determined through documentation released by Medi-Cal RX (DHCS, 2022a), a program providing pharmacy benefit coverage to all Medi-Cal beneficiaries, which is centrally administered by the California Department of Health Care Services (DHCS). As utilization numbers were not available from Medi-Cal RX, for this analysis, CHBRP relied on analysis of Medi-Cal managed care plan reimbursement for the relevant HCPCS codes (from 2021, the period immediately prior to Medi-Cal RX providing coverage for the benefit) to estimate baseline utilization of SMBP devices.

The rates for utilization from baseline cover all SMBP devices and device-related services referenced by SB 694. That is, baseline utilization numbers do not differentiate between users and rates (for instance, a utilization rate of 3 per 1,000 recipients could arise from one recipient getting three devices in a year or three recipients getting one device). Thus, there is no need to estimate the number of repeat users (due to breakage or loss) from the number of users. Multiplying the utilization rate by the number of users will provide an estimate of utilization regardless of whether or not some individuals get multiple devices.

Baseline coverage of SMBP device-related services (as defined by the codes cited in SB 694) was determined by a survey of the DMHC-regulated plans and County Organized Health Systems (COHS) enrolling Medi-Cal beneficiaries in managed care. As necessary, CHBRP extrapolated from responses of similarly situated plans. For this analysis, CHBRP relied on analysis of Medi-Cal managed care plan reimbursement for the relevant CPT[®] codes to estimate baseline utilization of the SMBP device-related services. This analysis has assumed that Medi-Cal beneficiaries would gain benefit coverage postmandate for the device-related services at the same rates as beneficiaries who already had coverage.

At baseline, there are four groups of Medi-Cal beneficiaries:

i) Those who have the SMBP devices covered through the centrally administered Medi-Cal RX program and who have both device-related services covered under their managed care plans;

- ii) Those who have the SMBP devices covered through the centrally administered Medi-Cal RX program as well as the education/calibration service covered under their managed care plan, but no coverage for the 30-day data collection service;
- iii) Those who have the SMBP devices covered through the centrally administered Medi-Cal RX program as well as the service covered under their managed care plan for the 30-day data collection service, but no coverage for the education/calibration; and
- iv) Those who have the SMBP devices covered through the centrally administered Medi-Cal RX program but no coverage for either service.

Postmandate, coverage for some beneficiaries would change to be compliant with SB 694, making it so that all beneficiaries will have coverage for both services as well as for the devices. Because the reimbursement opportunities for providers do not change for those who already have the full coverage (group i), there will be no change in utilization. For those who have coverage for the SMBP devices and education/calibration but not for data collection (group ii), utilization of SMBP devices and training education will not change but there will be some increase in use of the data collection service. The increase in utilization for the data collection is estimated using the utilization rates for those who already have coverage (group i and iii). For those who have coverage for the SMBP devices and data collection but not for education/calibration (group iii), utilization of SMBP devices and training education will not change but there will be some increase for the SMBP devices and data collection but not for education/calibration (group iii), utilization of SMBP devices and training education will not change but there will be some increase in use of the data collection service. The increase in utilization for the education/calibration (group iii), utilization of SMBP devices and training education will not change but that there will be some increase in use of the data collection service. The increase in utilization for the education/calibration is estimated using the utilization rates for those who already have coverage (group i, ii).

Baseline and Postmandate Benefit Coverage

SB 694 would require coverage for devices (monitors and cuffs) and two device-related services: education/calibration and data collection. It would not alter coverage for devices but would extend coverage for the services to some beneficiaries (see Table 1).

At baseline, all Medi-Cal beneficiaries have coverage for the SMBP devices (monitors and cuffs). There is no change in benefit coverage, postmandate, for Medi-Cal beneficiaries accessing coverage for an SMBP device.

At baseline, 91% Medi-Cal beneficiaries have coverage for the SMBP device-related education/calibration service, through their DMHC-regulated plan or through their County Organized Health System (COHS). Therefore, coverage of the education/calibration service postmandate would increase for 9% of Medi-Cal beneficiaries.

At baseline, 74% of Medi-Cal beneficiaries have coverage for the SMBP device-related 30-day data collection service, through their DMHC-regulated plan or through their County Organized Health System (COHS). Postmandate, all would. Therefore, coverage of the data collection service postmandate would increase for 26% of Medi-Cal beneficiaries.

Baseline and Postmandate Utilization

SB 694 would make no measurable change in utilization of the SMBP devices (monitors and cuffs). As shown in Table 1, use is expected to remain unchanged at 27,080 (so about 0.2% of Medi-Cal beneficiaries accessing coverage for a device). This statement is based on the assumption that, because the devices are currently available and the bill contains no provision or funding for outreach/promotion of the devices, there is no change in the incentives facing the providers or the Medi-Cal beneficiaries who are potential recipients of the devices and services, and thus no change in utilization is expected.

While coverage (and utilization) of the SMBP devices is not expected to change, there would be an increase in both coverage and utilization for education/calibration and 30-day data collection services. As

shown in Table 1, coverage for the education/calibration service would increase from 91% at baseline to 100% postmandate, and coverage for the data collection service would increase from 74% at baseline to 100%. This will result in an additional coverage for 986,130 and 2,848,820 for the services related to the devices.

To estimate the utilization that is expected in education/calibration service for the 9% of Medi-Cal beneficiaries who would gain coverage postmandate, the number of persons with new coverage (986,130) was multiplied by the utilization rate for those who were already covered. At baseline, utilization rate of education/calibration service for those with coverage was .01% of total beneficiaries or 4% of beneficiaries who received the devices. Postmandate, the utilization for the 986,130 who received additional coverage would be 110 services. The total service use would increase postmandate from 1,010 to 1,120, an increase of 10.89% (Table 1).

To estimate the utilization that is expected in 30-day data collection service for the 26% of Medi-Cal beneficiaries who would gain coverage postmandate, the number of persons with new coverage (2,848,820) was multiplied by the utilization rate for those who were already covered. At baseline, the utilization rate of education/calibration service for those with coverage was .001% of total beneficiaries or .05% of beneficiaries who received the devices. Postmandate, the utilization for the 2,848,820 who received additional coverage would be 40 services. The total service use would increase postmandate from 130 to 170, an increase of 30.8% (Table 1).

In sum, there would be no increase in use of devices postmandate, an increase in education/calibration of 110 services, and an increase in 30-day data collection of 40 services.

Baseline and Postmandate Expenditures

As noted in Table 1, unit costs (the amounts providers can receive for providing the devices and the services) are limited to \$43 for the device, \$14 for the education/calibration service, and \$11 for the 30-day data collection service. Unit costs for the devices was established though Medi-Cal public information. Unit costs for the services were established though review of reimbursements for the relevant CPT codes¹⁴ by Medi-Cal managed care plans. As noted in Table 1, increased utilization at these rates would raise total 2024 expenditures by Medi-Cal for enrollment of beneficiaries in managed care from \$36,606,800,000 to \$36,606,802,000, an increase of \$2,000 (0.000005%).

Postmandate Administrative Expenses

Given the small change in utilization and overall cost (\$2,000) postmandate, there is expected to be only a minimal (<.01%) change postmandate on administrative expenses.

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

No change is expected in the number of uninsured persons.

Changes in Public Program Enrollment

No change is expected in the public program enrollment.

¹⁴ CPT copyright 2023 American Medical Association. All rights reserved.

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

No cost shifting is expected from this legislation.

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, SB 694 would mandate Medi-Cal coverage of self-measured blood pressure (SMBP) devices, patient education and training for using the device, and data collection services (minimum 12 readings over a 30-day period).

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 impact¹⁵ of SB 694 on health outcomes. See *Long-Term Impacts* for additional information.

Estimated Public Health Outcomes

Although SMBP devices are found to be medically effective in helping people lower their blood pressure values, CHBRP concludes that passage of SB 694 would have no measurable short-term public health impact due to a marginal increase in previously low levels of utilization. As described in Table 1, 91% of enrollees have coverage for SMBP education/calibration services at baseline; however, utilization for this service is very low (1,010 education/calibration services/year). Postmandate, it is expected that utilization would increase slightly to 1,120 education/calibration services. For 30-day data collection services, 74% of enrollees have coverage at baseline; however, utilization for this service is also very low (130/year). Postmandate, it is expected that utilization of these services would increase to 170 30-day data collection services/year. For these reasons, CHBRP also concludes that SB 694 would have no measurable impact on disparities in health outcomes (by gender, race/ethnicity, sexual orientation/gender identity, or other determinants) in the first 12 months. It also would have no impact on premature death and societal economic losses.

Potential Harms from SB 694

When data are available, CHBRP estimates the marginal change in relevant harms associated with interventions affected by the proposed mandate. In the case of SB 694, there is insufficient evidence to suggest that an increase in the use of SMBP devices would increase harms.

¹⁵ CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of SB 694, 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

In the long term, whether utilization will increase is unknown, but with expanded public health promotion, there is potential for increased utilization of self-measured blood pressure (SMBP) devices.

Cost Impacts

In the long term, cost increases are unlikely if the estimates of minimal increases in the short term are sustained.

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments), whereas 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 disparities, premature death, and economic loss.

In the case of SB 694, CHBRP estimates minimal change in utilization in the first year due to prior coverage of SMBP devices and low utilization (see *Benefit Coverage, Utilization, and Cost Impacts* for additional information).

There is evidence that Medi-Cal beneficiaries with hypertension who receive an SMBP device may be better able to lower their blood pressure values (see *Medical Effectiveness* for additional information).

Although CHBRP estimates minimal change in utilization in the first year, Medi-Cal beneficiaries with hypertension who receive and use an SMBP device may be better able to lower their blood pressure values. Lower blood pressure (even if not fully controlled) is associated with better cardiovascular outcomes: fewer strokes, less cardiovascular disease, and less kidney failure (Whelton, 2017). Therefore, there is potential for a long term public health impact should awareness of coverage and subsequent utilization expand among Medi-Cal providers and beneficiaries.

APPENDIX A TEXT OF BILL ANALYZED

On February 16, 2023, the California Senate Committee on Health requested that CHBRP analyze SB 694, as introduced on February 16, 2023.

SENATE BILL

NO. 694

Introduced by Senator Eggman

February 16, 2023

An act to add Section 14132.967 to the Welfare and Institutions Code, relating to Medi-Cal.

LEGISLATIVE COUNSEL'S DIGEST

SB 694, as introduced, Eggman. Medi-Cal: self-measured blood pressure devices and services. Existing law establishes the Medi-Cal program, which is administered by the State Department of Health Care Services and under which qualified low-income individuals receive health care services. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions.

Existing law sets forth a schedule of benefits under the Medi-Cal program, including pharmacy benefits (Medi-Cal Rx) and durable medical equipment. The department announced that, effective June 1, 2022, personal home blood pressure monitoring devices, and blood pressure cuffs for use with those devices, are a covered benefit under Medi-Cal Rx as a pharmacy-billed item.

This bill would make self-measured blood pressure (SMBP) devices and SMBP services, as defined, covered benefits under the Medi-Cal program for the treatment of high blood pressure. The bill would state the intent of the Legislature that those covered devices and services be consistent in scope with devices and services that are recognized under specified existing billing codes or their successors. The bill would condition implementation of that coverage on receipt of any necessary federal approvals and the availability of federal financial participation.

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

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

SECTION 1. The Legislature finds and declares all of the following:

(a) In May 2022, the State Department of Health Care Services announced that, effective June 1, 2022, personal home blood pressure monitoring devices, and blood pressure cuffs for use with those devices, would be a covered benefit under Medi-Cal Rx as a pharmacy-billed item.

(b) Various states across the country provide coverage under their Medicaid state plans for selfmeasured blood pressure (SMBP) devices or SMBP services, or both. Those benefits are billed using the established billing codes of Healthcare Common Procedure Coding System (HCPCS) Codes A4670 and A4663 and Current Procedural Terminology (CPT) Codes 99473 and 99474.

(c) The Legislature seeks to statutorily cover, as benefits under the Medi-Cal program, not only SMBP devices but also SMBP services, for purposes of promoting the health of Medi-Cal beneficiaries with high blood pressure (hypertension).

SEC. 2. Section 14132.967 is added to the Welfare and Institutions Code, immediately following Section 14132.966, to read:

14132.967. (a) (1) Self-measured blood pressure (SMBP) devices shall be a covered benefit under the Medi-Cal program for the treatment of high blood pressure (hypertension).

(2) For purposes of this section, "SMBP device" includes, but is not limited to, an automated blood pressure monitor or a blood pressure cuff.

(3) It is the intent of the Legislature that these covered SMBP devices be consistent in scope with devices that are recognized under Healthcare Common Procedure Coding System (HCPCS) Code A4670 or A4663, or their respective successors.

(b) (1) SMBP services shall be a covered benefit under the Medi-Cal program for the treatment of high blood pressure (hypertension).

(2) For purposes of this section, "SMBP service" includes, but is not limited to, staff time for SMBP using a device validated for clinical accuracy, patient education and training, device calibration, separate self-measurements, collection of daily reports by the patient or caregiver to the health care provider, or communication of blood pressure readings and treatment plans to the patient.

(3) It is the intent of the Legislature that covered SMBP services be consistent in scope with services that are recognized under Current Procedural Terminology (CPT) Code 99473 or 99474, or their respective successors.

(c) This section shall be implemented only to the extent that any necessary federal approvals are obtained and federal financial participation is available.

APPENDIX B LITERATURE REVIEW METHODS

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

Studies of the effects of SMBP devices and SMBP device-related services were identified through searches of PubMed and Scopus. Websites maintained by the following organizations were also searched: Agency for Healthcare Research and Quality, US Preventive Services Task Force, Centers for Disease Control, and California Open Data. Search was limited to abstracts of studies published in English. The search was limited to studies published from 2018 to present. CHBRP relied on systematic reviews for findings from studies published prior to 2018.

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.

Medical Effectiveness Review

The medical effectiveness literature review returned abstracts for 392 articles, of which 43 were reviewed for inclusion in this report. A supplementary literature search identified an additional 11 articles that were also reviewed for potential inclusion. A total of 14 studies were included in the medical effectiveness review for SB 694.

Medical Effectiveness 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*.¹⁶ 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 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;
- Inconclusive evidence; and
- Insufficient evidence.

¹⁶ Available at: <u>https://www.chbrp.org/about/analysis-methodology/medical-effectiveness-analysis</u>.

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the <u>large majority</u> 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 <u>majority</u> 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 *inconclusive 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 (* indicates truncation of word stem

hypertensive hypertension high blood pressure blood pressure determination blood pressure monitor* blood pressure cuff* telemonitor* out-of-office home monitor* home blood pressure measure* self-monitor* self-measure* self-assessment self-care counseling educat* learning patient information patient training patient compliance consumer health information teach-back communication emergency service* emergency department

APPENDIX C OTHER SMBP DEVICE-RELATED SERVICES

As discussed in the *Policy Context* section, through reference to specific billing codes, SB 694 would require coverage of self-measured blood pressure (SMBP) devices and coverage of two SMBP device-related services for Medi-Cal beneficiaries for the treatment of hypertension.

- SMBP devices (monitors and cuffs) as defined by two Healthcare Common Procedure Coding System (HCPCS) codes:
 - A4670 automatic blood pressure monitor
 - A4663 blood pressure cuff
- Two SMBP device-related services as defined by two Current Procedural Terminology (CPT) codes:
 - 99473 education/calibration: patient training and device calibration (billing allowed once per device)
 - 99474 30-day data collection: separate self-measurements of two readings 1 minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver (billing allowed once per calendar month)

As discussed in the *Medical Effectiveness* section, there is insufficient evidence on the impact of the two SMBP device-related services that SB 694 would require plans and policies to cover. However, there is existing evidence on other services related to the use of SMBP devices that are not required under SB 694, such as telemonitoring.¹⁷ These other SMBP device-related services are not included in the discussion of evidence of effectiveness in the main body of the report because education/calibration and 30-day data collection are not the foci of the interventions studied. CHBRP discusses the findings of these studies in this appendix because many of the interventions involve some form of patient education, device calibration, and/or data collection.

Impact of use of SMBP device-related services that exceed SB 694's requirements on blood pressure values and blood pressure control

As mentioned in the *Medical Effectiveness* section, the American Heart Association and the American Medical Association issued a joint policy statement on SMBP in 2020 based on evidence gathered from eight meta-analyses published after 2008 that compared the effectiveness of SMBP and SMBP device-related services with usual care (Shimbo et al., 2020). The types of SMBP device-related services provided to people enrolled in the studies included in the meta-analyses varied and exceeded the services for which SB 694 would require coverage. In these studies, usual care was defined as care that did not include SMBP. The findings from five of the eight studies (Bray et al., 2010; Duan et al., 2017; Omboni et al., 2013; Tucker et al., 2017; Uhlig et al., 2013) are summarized below.¹⁸

Table 6 presents findings from the five meta-analyses, two individual patient data meta-analyses¹⁹ (Bryant et al., 2020; Sheppard et al., 2020), and one RCT (Cairns et al., 2018) that assessed the impact of using SMBP devices plus SMBP device-related services that exceed those for which SB 694 would require coverage on BP values and BP control.

¹⁷ SMBP with telemonitoring refers to self-measured BP by a patient using an electronic automated BP monitor and a telecommunication system by which BP values are transmitted for review by the patient's provider. SMBP (without telemonitoring) also refers to self-measured BP by a patient using an electronic automated BP monitor, however, BP values are manually recorded by the patient who then shares the data with their provider.

¹⁸ The other three meta-analyses are not discussed in this appendix because they synthesized studies of the use of SMBP devices without use of SMBP device-related services.

¹⁹ Individual patient data meta-analyses are studies that combine patient level data from multiple studies to estimate overall effects of interventions. Traditional meta-analyses estimate overall findings based on the mean effects of interventions on the populations studied.

Table 6. Summary of Evidence of Medical Effectiveness of Use of SMBP Device-related Services that Exceed SB 694's Requirements on
Blood Pressure Values and Blood Pressure Control

		BP V	alues	BP Control		
Study	Comparison Type	Result	Finding	Result	Finding	
Bray et al. (2010) (Meta-analysis of 25 RCTs)	SMBP + co- intervention vs. usual care	Systolic -3.82 mm Hg reduction (95% Cl: -5.61, -2.03) Diastolic -1.45 mm Hg reduction (95% Cl: -1.95, -0.94)	Statistically significant differences	RR of meeting target BP: 1.09 (95% CI: 1.02, 1.16)	Statistically significant increase in chance of meeting target BP with SMBP	
Omboni et al. (2013) (Meta-analysis of 23 RCTs)	SMBP tele- monitoring vs. usual care	Systolic -4.71 mm Hg reduction (95% Cl: - 6.18, -3.24) Diastolic -2.45 mm Hg reduction (95% Cl: -3.33, -1.57)	Statistically significant differences	RR of controlled BP: 1.16 (95% CI: 1.04, 1.29)	Statistically significant larger improvement in BP control with SMBP telemonitoring	
Uhlig et al. (2013) (Meta-analysis of 26 prospective comparative studies)	SMBP + co- intervention vs. usual care	Systolic mean reduction ranging from -3.4 to -8.9 mm Hg Diastolic mean reduction ranging from -1.9 to -4.4 mm Hg	Lower systolic and diastolic BP with use of SMBP plus co- intervention vs. usual care (statistical significance not reported)	Not reported	Not reported	
	SMBP + co- intervention vs. SMBP alone	Not reported	No evidence of a statistically significant difference	Not reported	Not reported	
Duan et al. (2017) (Meta-analysis of 46 RCTs)	SMBP tele- monitoring vs. usual care	Systolic -2.33 mm Hg reduction (95% Cl: -3.59, -1.07) Diastolic -0.44 mm Hg (95% Cl: -1.34, 0.47)	Statistically significant difference for systolic BP but not for diastolic BP	Improvement in BP control: 52.07% SMBP telemonitoring vs. 43.82% usual care	Statistically significant larger improvement in BP control with SMBP telemonitoring	
Tucker et al. (2017) (Meta-analysis of 25 RCTs)	SMBP + co- interventions vs. usual care	Separate results by intervention level (SMBP with web/phone feedback, SMBP with web/phone feedback and education, SMBP with	Statistically significant difference for systolic BP at all intervention levels Statistically significant difference for diastolic BP at SMBP with web/phone feedback and	RR of uncontrolled BP: 0.90 (95% CI: 0.69, 1.15) for SMBP with web/phone feedback RR of uncontrolled BP: 0.57 (95% CI: 0.44, 0.73) for SMBP with	Risk of having uncontrolled BP decreased as intensity level of co-interventions increased	

		BP Values		BP Control		
Study	Comparison Type	Result	Finding	Result	Finding	
		counseling/ telecounseling)	education, and SMBP with counseling/ telecounseling levels only	web/phone feedback and education RR 0.44 (95% CI: 0.34, 0.57) for SMBP with counseling/ telecounseling		
Cairns et al. (2018) (RCT of 91 postpartum women)	SMBP tele- monitoring vs. usual care	Separate results by week of follow-up (4, 6, 12, 26 weeks)	Statistically significant difference for systolic BP at 6 weeks only Statistically significant difference for diastolic BP at all follow-up intervals	Separate results by week of follow-up (4, 6, 12, 26 weeks)	Greater likelihood of BP control at 6 weeks with SMBP telemonitoring	
Bryant et al. (2020) (Individual patient data meta-analysis of 4 RCTs)	SMBP tele- monitoring vs. usual care	Systolic –5.4 mm Hg reduction (95% Cl: –6.9, –3.8) Diastolic –1.5 mm Hg reduction (95% Cl: –2.2, –0.7)	Statistically significant differences	5-year BP control rate: 72.1% with SMBP (projected, if participants continued receiving SMBP all 5 years) vs. 39.0% with SMBP (projected, if participants stopped receiving SMBP after 12 months and started receiving usual care) vs. 33.4% with usual care alone	SMBP projected to be higher % controlled if BP process improvements and adherence sustained for 5 years	
Sheppard et al. (2020) (Individual patient data meta-analysis of 16 RCTs)	SMBP + co- intervention vs. usual care	Mixed findings	More intensive interventions associated with greater reduction in systolic BP among people with diabetes or obesity but not among people with chronic kidney disease, coronary heart disease, or stroke	Mixed findings	More intensive interventions associated with lower odds of uncontrolled BP among people with diabetes or obesity but not among people with chronic kidney disease, coronary heart disease, or stroke	

Source: California Health Benefits Review Program, 2023.

Key: BP = blood pressure; CI = confidence interval; OR = odds ratio; RCT = randomized controlled trial; RR = relative risk; SMBP = self-measured blood pressure.

Blood pressure values

Three of the meta-analyses (Bray et al., 2010; Duan et al., 2017; Omboni et al., 2013) and two of the individual patient data meta-analyses (Bryant et al., 2020; Tucker et al., 2017) found that use of SMBP device-related services that exceed SB 694's requirements was associated with a statistically significant reduction in systolic BP relative to usual care at one or more time intervals post intervention. In these meta-analyses, mean decreases in systolic BP ranged from -2.3 mm Hg (Duan et al., 2017) to -5.4 mm Hg (Bryant et al., 2020). These reductions in mean systolic BP in the populations studied are large enough to be clinically significant. Uhlig et al. (2013) also found that use of SMBP device-related services that exceed the requirements of SB 694 was associated with a reduction in systolic BP relative to usual care; however, statistical significance was not reported. Sheppard et al. (2020) reported the impact of the intensity of SMBP device-related services on mean changes in systolic BP among people with hypertension who had specific comorbidities. The authors found that more intensive interventions were associated with greater reduction in systolic BP among people with diabetes or obesity but not among people with chronic kidney disease, coronary heart disease, or stroke. An RCT conducted in England that enrolled postpartum women with gestational hypertension or preeclampsia who required antihypertensive treatment after birth found that use of SMBP devices with telemonitoring was associated with a reduction in systolic BP at 6 weeks post intervention relative to usual care but not at other time intervals (Cairns et al., 2018).

Two of the meta-analyses (Bray et al., 2010; Omboni et al., 2013) and one of the individual patient data meta-analyses (Bryant et al., 2020) found that use of SMBP device-related services that exceed SB 694's requirements was associated with a statistically significant reduction in diastolic BP relative to usual care. In these meta-analyses, mean decreases in diastolic BP ranged from -1.5 mm Hg (Bryant et al., 2020) to -2.5 mm Hg (Omboni et al., 2013). Uhlig et al. (2013) also found that use of SMBP device-related services that exceed the requirements of SB 694 was associated with a reduction in diastolic BP relative to usual care; however, statistical significance was not reported. One meta-analysis concluded that there was no statistically significant difference in diastolic BP between people using SMBP device-related services that exceed the requirements of SB 694 and people receiving usual care (Duan et al., 2017). One individual patient data meta-analysis reported that the impact of SMBP device-related services that exceed the requirements of SB 694 on diastolic BP varied across the types of interventions studied (Tucker et al., 2017). The RCT that enrolled postpartum women with gestational hypertension or preeclampsia reported that use of SMBP devices with telemonitoring was associated with reductions in diastolic BP at 4, 6, 12, 26 weeks postintervention relative to usual care (Cairns et al., 2018).

Summary of findings regarding the impact of use of SMBP device-related services that exceed SB 694's requirements on blood pressure values: There is a *preponderance of evidence* from five metaanalyses, two individual patient data meta-analyses, and one RCT that use of SMBP device-related services that exceed the requirements of SB 694 is associated with statistically significant reductions in systolic and diastolic BP relative to usual care.

Figure 13. Impact of Use of SMBP Device-Related Services that Exceed SB 694's Requirements on Blood Pressure Values

T EFFECTIVE						EFFECTI
					٨	
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	PREPONDERANCE	Clear and Convincing

Blood pressure control

Four of the meta-analyses, two individual patient data meta-analyses, and one RCT examined the impact of SMBP device-related services that exceed SB 694's requirements on BP control relative to usual care.

All four meta-analyses (Bray et al., 2010; Duan et al., 2017; Omboni et al., 2013; Tucker et al., 2017) found that people who received SMBP device-related services that exceed the requirements of SB 694 were more likely to achieve BP control (as defined by the studies included in the meta-analyses) than people who received usual care. One individual patient data meta-analysis projected that SMBP with telemonitoring would result in a higher percentage of patients attaining BP control if BP monitoring and adherence to treatment regimens were sustained for 5 years (Bryant et al., 2020). Sheppard et al. (2020) examined the impact of the intensity of SMBP device-related services on people with hypertension who had specific comorbidities. The authors found that more intensive interventions were associated with a greater likelihood of achieving BP control among people with diabetes or obesity but not among people with chronic kidney disease, coronary heart disease, or stroke. The RCT that enrolled postpartum women with gestational hypertension or preeclampsia reported that use of SMBP devices with telemonitoring was associated with a greater likelihood of BP control at 6 weeks postintervention relative to usual care (Cairns et al., 2018).

Summary of findings regarding the impact of use of SMBP device-related services that exceed SB 694's requirements on blood pressure control: There is a *preponderance of evidence* from four metaanalyses, two individual patient data meta-analyses, and one RCT that use of SMBP device-related services that exceed SB 694's requirements is associated with greater likelihood that people will attain BP control (as defined by prespecified thresholds) relative to usual care.

Figure 14. Impact of Use of SMBP Device-Related Services that Exceed SB 694's Requirements on Blood Pressure Control

T EFFECTIVE						EFFECTIV
					٨	
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	PREPONDERANCE	Clear and Convincing

Impact of use of SMBP device-related services that exceed SB 694's requirements on complications of hypertension

CHBRP did not identify any studies published within the last 5 years that directly assessed the impact of use of SMBP device-related services that exceed SB 694's requirements on complications of hypertension (e.g., heart attack, stroke, kidney disease). Thus, CHBRP concluded that there is *insufficient evidence* on the impact of these SMBP device-related services on complications of hypertension. However, the absence of evidence does not indicate that SMBP device-related services that exceed SB 694's requirements have no effect on complications of hypertension. These SMBP device-related services may have an indirect effect on the complications of hypertension because their use may be associated with reduction of BP values and better BP control, which may lower the risk of complications (Shimbo et al., 2020).

Summary of findings regarding the impact of use of SMBP device-related services that exceed SB 694's requirements on complications of hypertension: There is *insufficient evidence* to assess the direct impact of use of SMBP device-related services that exceed the requirements of SB 694 on complications of hypertension.

Figure 15. Impact of Use of SMBP Device-Related Services that Exceed SB 694's Requirements on Complications of Hypertension

NOT EFFECTIVE		INSU	FFICIENT EVID	ENCE		EFFECTIVE
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing

Impact of use of SMBP device-related services that exceed SB 694's requirements on quality of life

Two meta-analyses compared SMBP with telemonitoring versus usual care and assessed the impact of SMBP device-related services that exceed those for which SB 694 would require coverage on quality of life. Duan et al. (2017) found no significant differences in the physical and mental health components of quality of life between participants in the SMBP with telemonitoring group and participants in the usual care group. Omboni et al. (2013) detected significantly higher scores for the physical component of quality of life in the SMBP with telemonitoring group compared to the usual care group, but there were no significant differences between groups for the mental health component of quality of life. Although the meta-analysis by Duan et al. (2017) included many studies that were included in the meta-analysis by Omboni et al. (2013), the authors reached different conclusions largely due to differences in the methods they used to estimate their meta-analyses. Moreover, Duan et al. (2017) included studies involving nonhypertensive participants (in addition to hypertensive patients), whereas Omboni et al. (2013) included studies involving hypertensive participants only.

Another meta-analysis (Uhlig et al., 2013) discussed studies that assessed quality of life outcomes, none of which found any difference in quality of life between SMBP alone versus usual care, SMBP plus additional support versus usual care, or SMBP plus additional support versus SMBP alone or with less intense additional support.

Cairns et al. (2018) found no differences in participants' self-reported quality of life at 6 weeks or 6 months between the SMBP with telemonitoring group and the usual care group in their RCT of postpartum women with gestational hypertension or preeclampsia.

Summary of findings regarding the impact of use of SMBP device-related services that exceed SB 694's requirements on quality of life: There is *limited evidence* that use of SMBP device-related services that exceed SB 694's requirements is not effective at improving quality of life compared to usual care based on three meta-analyses and one RCT.

Figure 16. Impact of Use of SMBP Device-Related Services that Exceed SB 694's Requirements on Quality of Life



Impact of use of SMBP device-related services that exceed SB 694's requirements on use of acute care services

CHBRP did not identify any studies published within the last 5 years that directly assessed the impact of using SMBP device-related services that exceed SB 694's requirements on use of acute care services, such as emergency department visits or inpatient admissions. Thus, CHBRP concluded that there is *insufficient evidence* on the impact of these SMBP device-related services on use of acute care services.

However, the absence of evidence does not indicate that SMBP has no effect on acute care use. SMBP device-related services that exceed the requirements of SB 694 may have an indirect effect on use of acute care services because their use may be associated with reduction of BP values and better BP control, which may lower the need for acute care services.

Summary of findings regarding the impact of use of SMBP device-related services that exceed SB 694's requirements on use of acute care services: There is *insufficient evidence* to assess the direct impact of use of SMBP device-related services that exceed SB 694's requirements on the use of acute care services.

Figure 17. Impact of Use of SMBP Device-Related Services that Exceed SB 694's Requirements on Use of Acute Care Services

NOT EFFECTIVE		EFFECTIVE				
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing

Summary of Findings

The types of SMBP device-related services provided to people enrolled in the studies discussed in Appendix C varied and exceeded the services for which SB 694 would require coverage. Collectively, there is a *preponderance of evidence* that, relative to usual care, SMBP device-related services that exceed the requirements of SB 694 are associated with reduction in BP and improvement in BP control. However, these findings may not generalize to SB 694. There is *insufficient evidence* to assess the direct impact of use of SMBP device-related services that exceed the requirements of SB 694 on complications of hypertension or use of acute care services. There is *limited evidence* that use of these SMBP device-related services is not effective at improving quality of life compared to usual care.

APPENDIX D COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

With the assistance of CHBRP's contracted actuarial firm, Milliman, Inc, the cost analysis presented in this report was prepared by the faculty and researchers connected to CHBRP's Task Force with expertise in health economics.²⁰ 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.²¹

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

Analysis-Specific Data Sources

Baseline coverage for self-measured blood pressure (SMBP) devices (as defined by the codes cited in SB 694) was determined through documentation released by Medi-Cal RX (DHCS, 2022a), a program providing pharmacy benefit coverage to all Medi-Cal beneficiaries, which is centrally administered by the California Department of Health Care Services (DHCS). Unit cost as supported by Medi-Cal RX was determined through review of the Covered Personal Blood Pressure Monitoring Devices and Blood Pressure Cuffs spreadsheet made available by DHCS (DHCS, 2022b). As utilization numbers were not available from Medi-Cal RX, for this analysis, CHBRP relied on analysis of Medi-Cal managed care plan utilization for the relevant Healthcare Common Procedure Coding System (HCPCS) codes (from the period prior to Medi-Cal RX providing coverage for the benefit) to estimate baseline utilization of SMBP devices.

Baseline coverage of SMBP device-related services (as defined by the codes cited in SB 694) was determined by a survey of the DMHC-regulated plans and County Organized Health Systems (COHS) enrolling Medi-Cal beneficiaries in managed care. Responses to this survey represented 35% of managed Medi-Cal beneficiaries. For this analysis, CHBRP relied on analysis of Medi-Cal managed care plan reimbursement for the relevant CPT[®] codes to estimate baseline unit cost of the SMBP device-related services.

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Detailed Cost Notes Regarding Analysis-Specific Caveats and Assumptions

General assumptions are noted in the body of this report. Additional assumptions are noted below.

CHBRP assumed the non–DMHC-regulated, dually eligible Medi-Cal members (Duals) have premiums and coverage similar to the 65 and over members in DMHC-regulated managed Medi-Cal plans and non–DMHC-regulated county organized health system (COHS) plan members have premiums and coverage similar to the under 65 members in DMHC-regulated managed Medi-Cal plans.

 ²⁰ CHBRP's authorizing statute, available at <u>https://chbrp.org/about_chbrp/index.php</u>, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
 ²¹ See method documents posted at <u>https://www.chbrp.org/about/analysis-methodology/cost-impact-analysis;</u> in

particular, see 2022 Cost Analyses: Data Sources, Caveats, and Assumptions.

Methodology and Assumptions for Baseline Benefit Coverage

The population subject to the mandated offering includes all individuals with health insurance administered through Medi-Cal.

As of June 1, 2022, SMBP devices are a covered benefit under Medi-Cal RX. CHBRP assumed all Medi-Cal enrollees have coverage for blood pressure devices.

Because SMBP devices are a covered under Medi-Cal RX, CHBRP surveyed managed Medi-Cal organizations to determine the percentage of the population with coverage for the two SMBP device-related service CPT²² codes: 99473, 99474. Based on the survey results, 91% and 74% of enrollees have coverage for 99473 and 99474, respectively.

Methodology and Assumptions for Baseline Utilization

The average annual utilization for the four CPTs²³ were identified in Milliman's proprietary 2021 Milliman Consolidated Health Cost Guidelines Sources Database (CHSD) for Medicaid members in California. Due to low utilization of 99474, the utilization rate from the Medicaid population in New York was used in place of the California utilization rate.

The utilization rates were trended at 1% annually from 2021 to 2024.

CHBRP assumed enrollees without coverage for SMBP device-related services do not use SMBP device-related services.

Methodology and Assumptions for Baseline Cost

CHBRP calculated the average California commercial cost per service for SMBP-related services using Milliman's proprietary 2021 Consolidated Health Cost Guidelines[™] Sources Database (CHSD).

The commercial average unit cost for SMBP-related services were discounted 65% to estimate the Medicaid average cost per service, based on medical cost differentials (McBeth, 2021, Zuckerman, 2021).

The average unit cost for SMBP services were trended at 0.5% annually from 2021 to 2024.

The unit costs of blood pressure cuffs and personal home blood pressure devices are based on the median maximum allowable product costs published by Medi-Cal RX as of March 29, 2023. The unit cost of each product was weighted by the utilization of the SMBP device CPT⁴ codes. The median unit cost for SMBP devices was trended at 0.0% annually from 2023 to 2024.

Methodology and Assumptions for Baseline and Postmandate Cost Sharing

CHBRP assumed no cost sharing for any services.

Methodology and Assumptions for Postmandate Utilization

CHBRP assumed the utilization rate for enrollees with coverage postmandate is equal to the utilization rate for enrollees with coverage at baseline.

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²³ CPT copyright 2023 American Medical Association. All rights reserved.

Methodology and Assumptions for Postmandate Cost

CHBRP assumed the average cost per service would not change as a result of SB 694.

Second-Year Impacts on Benefit Coverage, Utilization, and Cost

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of SB 694 would have a substantially different impact on utilization of either the tests, treatments, or services for which coverage was directly addressed, the utilization of any indirectly affected utilization, or both. CHBRP reviewed the literature and consulted content experts about the possibility of varied second-year impacts and determined the second year's impacts of SB 694 would be substantially the same as the impacts in the first year (see Table 1). Minor changes to utilization and expenditures are due to population changes between the first year postmandate and the second year postmandate.

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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 researchers and analysts who are **Task Force 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, **Milliman**, 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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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.

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