

California Health Benefits Review Program

Analysis of California Senate Bill 839 Obesity Treatment Parity

A Report to the 2023–2024 California State Legislature

December 22, 2023



Key Findings

Analysis of California Senate Bill 839

Obesity Treatment Parity

Summary to the 2023–2024 California State Legislature, December 22, 2023



SUMMARY

Senate Bill (SB) 839 would require comprehensive coverage for obesity treatments, including intensive behavioral therapy (IBT), bariatric surgery, and the two groups of prescription drugs approved by the Food and Drug Administration (FDA) with an indication for weight management: glucagon-like peptide 1 (GLP-1) receptor agonists and non-GLP-1s. SB 839 would also require that cost sharing for obesity treatments not be different or separate from treatments for other illnesses, conditions, or disorders.

Benefit Coverage: At baseline, almost all enrollees have fully compliant coverage for IBT and bariatric surgery with cost-sharing parity. At baseline, for weight management, 86.8% have no coverage for GLP-1s and 10.1% have on-formulary coverage for at least one GLP-1 with cost-sharing parity. At baseline, for weight management, 64% have no coverage for non-GLP-1s and 32.5% have on-formulary coverage for at least one GLP-1 with cost-sharing parity. Postmandate, all would have fully compliant, on-formulary coverage for at least one GLP-1 and one non-GLP-1.

Medical Effectiveness: For adults, there is *clear and convincing evidence* that both FDA-approved GLP-1 and non-GLP-1 weight management drugs are effective adjuncts to usual care, that bariatric surgery is effective, and that IBT is effective.

Cost and Health Impacts: Almost no change would be expected in the use or impacts of bariatric surgery or IBT. There would be a 951% increase in use of GLP-1s and a 197% increase in use of non-GLP-1s, resulting in a total net annual expenditure increase of 0.9%. Increases in premium would result in 10,000 persons losing or dropping health insurance. The 124,000 enrollees newly using the drugs would experience a 5% to 15% body weight reduction. Reduced cardiovascular events would be expected in the second year, and maintained weight loss could reduce cardiovascular disease, hypertension (i.e., high blood pressure), type 2 diabetes, and certain types of cancer; as well as a reduction in downstream effects such as impacts on premature death.

BILL SUMMARY

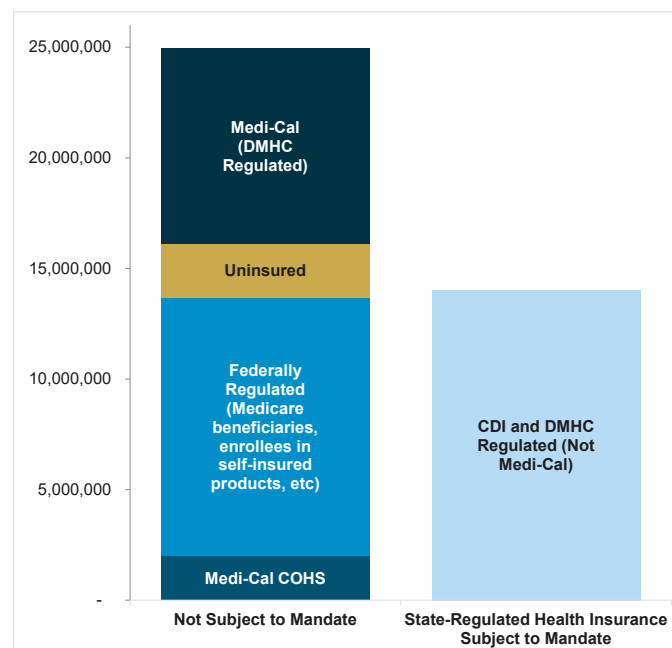
SB 839 would require comprehensive coverage for obesity treatments, including:

- Drugs approved by the FDA with an indication for chronic weight management — coverage criteria for the drugs could not be more restrictive than the FDA-approved indications;
- Bariatric surgery; and
- Intensive behavioral therapy (IBT).

SB 839 would also require that cost sharing for obesity treatments not be different or separate from treatments for other illnesses, conditions, or disorders.

Because SB 839 specifies “group and individual” plans and policies, the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans would not be subject to SB 839’s requirements.

Figure A. Health Insurance in CA



Source: California Health Benefits Review Program, 2023.

ANALYTIC APPROACH

Although the bill language could be interpreted as creating benefit coverage requirements for additional obesity tests, treatments, and services, this analysis focuses on the prescription drugs, surgeries, and behavioral therapy that seem most directly referenced in SB 839:

- The two groups of prescription drugs approved by the FDA with an indication for chronic weight management:
 - Glucagon-like peptide 1 (GLP-1) receptor agonists¹
 - Non-GLP-1s
- Bariatric surgeries
- Intensive behavioral therapy (IBT)

For the prescription drugs, CHBRP has assumed that SB 839 would require on-formulary coverage with cost sharing parity for one GLP-1 and one non-GLP-1.

CHBRP has assumed that existing supply chain issues for GLP-1s will be fully resolved in 2024 due to changes and increasing capacity in manufacturing, as well as another prescription drug coming to market.

CONTEXT

Obesity is a chronic health condition characterized by an increase in the size and amount of fat cells in the body. Healthcare providers screen for obesity by calculating patients' body mass index (BMI), which takes into account an individual's height and weight. Individuals with a BMI of 25 or higher are categorized as overweight and those with a BMI of 30 or higher are categorized as obese.

Causes of obesity are multifaceted and can include lifestyle habits, environment, socioeconomic factors, and individual characteristics such as genetics and metabolism.

There are many health consequences of obesity such as an increased risk of heart disease, diabetes, and certain cancers, as well as reduced life expectancy.

Nearly 3 million Californians with obesity are enrolled in health insurance that would be subject to SB 839. An additional 500,000 overweight Californians with comorbidities would also be subject to SB 839.

¹ One drug, Tirzepatide (Zepbound), is a dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1

IMPACTS

Medical Effectiveness

There is *clear and convincing evidence* that use of both GLP-1 and non-GLP-1 weight management drugs in addition to usual care (including standard diet and activity and lifestyle recommendations) is associated with greater weight loss in adults than usual care alone.

There is *limited evidence* that some GLP-1 and non-GLP-1 weight management drugs improve weight loss in adolescents.

There is *clear and convincing evidence* that bariatric surgery is effective in adults, with studies reporting that patients lose significantly more weight after surgery compared to patients who receive nonsurgical interventions.

There is *limited evidence* that bariatric surgery is effective for adolescents with obesity, with studies reporting that adolescents lose significantly more weight and reduced BMI after surgery compared to similar adolescents who do not have surgery.

There is *clear and convincing evidence* that adults who receive IBT for weight loss are more likely to achieve a ≥5% weight loss than adults who receive less intensive treatments.

There is *clear and convincing evidence* that IBT for weight loss is effective in reducing weight and BMI for children and adolescents.

Benefit Coverage, Utilization, and Cost

Benefit Coverage

At baseline, 99.9% of enrollees with health insurance that would be subject to SB 839 already have fully compliant coverage for IBT and bariatric surgery with parity in cost sharing. Therefore, there would be very limited change to coverage or cost sharing due to the enactment of SB 839.

At baseline, 10.1% of enrollees with health insurance that would be subject to SB 839 already have fully compliant coverage for GLP-1 weight management drugs with parity in cost sharing. Another 3.1% have coverage for the medication without parity in cost sharing, while the remaining 86.8% of enrollees with

health insurance that would be subject to SB 839 have no coverage for GLP-1 weight management drugs. Postmandate, all enrollees with health insurance that would be subject to SB 839 would have fully compliant coverage for GLP-1 weight management drugs with parity in cost sharing. These newly covered enrollees represent 90% of enrollees (an 887% increase from baseline).

At baseline, 32.5% of enrollees with health insurance that would be subject to SB 839 already have fully compliant coverage for non-GLP-1 weight management drugs with parity in cost sharing. Another 3.5% have coverage for the medication without parity in cost sharing, while the remaining 64.0% of enrollees with health insurance that would be subject to SB 839 have no coverage for non-GLP-1 weight management drugs. Postmandate, all enrollees with health insurance that would be subject to SB 839 would have fully compliant coverage for non-GLP-1 weight management drugs with parity in cost sharing. These newly covered enrollees represent 68% of enrollees (a 208% increase from baseline).

Unit Costs

There would be no expected increase in unit costs due to the enactment of SB 839. GLP-1 weight management drugs (\$845) and non-GLP-1 weight management drugs (\$331) would maintain the same average unit cost per year postmandate. However, average cost sharing would increase for GLP-1 weight management drugs by \$27 and decrease for non-GLP-1 weight management drugs by \$12. The increase in cost sharing for GLP-1 drugs would be driven by the plans that do not currently cover GLP-1 weight management drugs having higher coinsurance amounts than the plans that already cover GLP-1 weight management drugs. As utilization increases in those plans that had no coverage and higher coinsurance requirements, the average cost sharing would increase. There would also be no change in per-unit costs for bariatric surgery (\$29,522) or IBT (\$500) or their associated cost sharing because of existing coverage for all enrollees at parity.

Utilization

There would be no material change in utilization of IBT or bariatric surgery postmandate due to the existing 99.9% compliant benefit coverage at baseline. There is also no evidence that IBT or bariatric surgeries would increase due to the increased use of GLP-1 or non-GLP-1 weight management drugs.

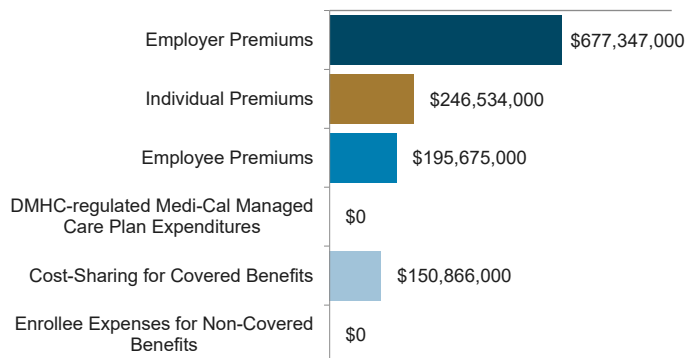
There are 2,972,677 enrollees with obesity and 513,625 overweight enrollees with comorbidities in plans subject to SB 839. At baseline, only 10,008 enrollees use GLP-1

weight management drugs, while 14,838 use non-GLP-1 weight management drugs. Postmandate, due to the 90 percentage point increase in coverage for GPL-1 and 68 percentage point increase in non-GLP-1 weight management drugs, 105,156 enrollees would be expected to use GPL-1 and 44,057 enrollees would be expected to use non-GLP-1 weight management drugs.

Expenditures

SB 839 would increase total net annual expenditures by \$1.27 billion or 0.9% for enrollees with plans and polices regulated by the California Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI). This is due to a \$1.12 billion increase in total health insurance premiums paid by employers and enrollees for newly covered benefits and a \$150.9 million increase in enrollee expenses for covered benefits. In the following year, the increase in estimated expenditures would be higher.

Figure B. Expenditure Impacts of SB 839



Source: California Health Benefits Review Program, 2023.

Uninsured Persons

Because the change in average premiums would exceed 1% for several health insurance market segments, CHBRP would expect a measurable change in the number of uninsured persons due to the enactment of SB 839, especially in markets where the enrollee bears the majority of any added premium costs. For example, despite an estimated 1.18% increase in the DMHC-regulated individual market, about 75% of the enrollees are in Covered California plans where tax credits are linked to the 2nd lowest silver premium available in the region, such that enrollees are partially protected from premium increases for new benefit mandates because they also cause the tax credits to increase commensurately. The premium increases in the CDI-regulated and DMHC-regulated California Public Employees' Retirement System (CalPERS) market segments are not above 1%, so CHBRP anticipates that coverage losses would be limited to enrollees in DMHC-

regulated plans, with a specific focus on individual market plans offered outside of Covered California where tax credits to subsidize the cost are unavailable.

Due to an estimated premium increase of greater than 1% due to SB 839 in several market segments, CHBRP estimates that the increases in premiums would cause more than 10,000 enrollees to lose or drop health insurance. This could lead to an increase in the uninsured of 0.43%, but the majority of newly uninsured would likely come from enrollees in the DMHC-regulated individual market and the DMHC-regulated small-group market where premium increases are more likely to be passed on as enrollee out-of-pocket premium costs rather than absorbed by federally funded tax credits or employer contributions to health insurance coverage.

Public Health

In the first year postmandate, 14 million enrollees with health insurance subject to SB 839 would experience a change in benefit coverage and 124,000 would newly utilize obesity treatments. As a result, these enrollees

would experience a 5% to 14% reduction in body weight and related health improvements, which is supported by evidence that obesity treatments are medically effective.

Long-Term Impacts

Although CHBRP anticipates initial year offsets related to fewer cardiovascular events, other reductions in utilization might occur in the long-term if people are able to continue taking GLP-1 drugs long-term and maintain weight loss, which would improve health status. These health impacts include a reduction in the overall prevalence of obesity and obesity-related chronic disease, including a reduction in cardiovascular disease, hypertension (i.e., high blood pressure), type 2 diabetes, and certain types of cancer; as well as a reduction in downstream effects such as impacts on premature death.

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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 www.chbrp.org.

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Table 1. Impacts of SB 839 on Benefit Coverage, Utilization, and Cost, 2024

	Baseline (2024)	Postmandate Year 1 (2024)	Increase/Decrease	Change Postmandate
Benefit Coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	22,842,000	22,842,000	0	0%
Total enrollees with health insurance subject to SB 839	14,025,000	14,025,000	0	0%
Percent of enrollees with fully compliant coverage and parity in cost sharing for GLP-1 drugs	10.1%	100.0%	90%	886.5%
Percent of enrollees with coverage and without parity in cost sharing for GLP-1 drugs	3.1%	0.0%	-3%	-100.0%
Percent of enrollees without coverage for GLP-1 drugs	86.8%	0.0%	-87%	-100.0%
Percent of enrollees with fully compliant coverage and parity in cost sharing for non-GLP-1 drugs	32.5%	100.0%	68%	207.7%
Percent of enrollees with coverage and without parity in cost sharing for non-GLP-1 drugs	3.5%	0.0%	-3%	-100.0%
Percent of enrollees without coverage for non-GLP-1 drugs	64.0%	0.0%	-64%	-100.0%
Percent of enrollees with fully compliant coverage and parity in cost sharing for bariatric surgery	99.9%	100.0%	0%	0.1%
Percent of enrollees with coverage and without parity in cost sharing for bariatric surgery	0.0%	0.0%	0%	(h)
Percent of enrollees without coverage for bariatric surgery	0.1%	0.0%	0%	(h)
Percent of enrollees with fully compliant coverage and parity in cost sharing for IBT for weight loss	99.9%	100.0%	0%	0.1%
Percent of enrollees with coverage and without parity in cost sharing for IBT for weight loss	0.0%	0.0%	0%	(h)
Percent of enrollees without coverage for IBT for weight loss	0.1%	0.0%	0%	(h)
Utilization and Cost				
Number of enrollees with obesity	2,972,677	2,972,677	-	0.00%
Number of overweight enrollees with comorbidities	513,625	513,625	-	0.00%

Number of enrollees using GLP-1 FDA-approved weight management drugs	10,008	105,156	95,148	950.73%
Average unit cost of FDA-approved GLP-1 weight management drugs	\$845	\$845	\$0	0.00%
Average cost sharing for FDA-approved GLP-1 weight management drugs	\$91	\$117	\$27	29.44%
Number of enrollees using non-GLP-1 weight management drugs	14,838	44,057	29,219	196.92%
Average unit cost of FDA-approved non-GLP-1 weight management drugs	\$331	\$331	\$0	0.00%
Average cost sharing for FDA-approved non-GLP-1 weight management drugs	\$58	\$46	-\$12	-21.12%
Number of enrollees receiving bariatric surgery	6,719	6,724	5	0.08%
Average unit cost of bariatric surgery	\$29,522	\$29,522	\$0	0.00%
Average cost sharing for bariatric surgery	\$4,046	\$4,045	-\$1	-0.03%
Number of enrollees receiving IBT for weight loss	27,112	27,127	14	0.05%
Average unit cost of IBT	\$500	\$500	\$0	0.00%
Average cost sharing for IBT	\$1	\$1	\$0	1.26%
Expenditures				
<i>Premiums</i>				
Employer-sponsored (b)	\$57,647,993,000	\$58,275,731,000	\$627,738,000	1.09%
CalPERS employer (c)	\$6,158,262,000	\$6,207,871,000	\$49,609,000	0.81%
Medi-Cal (excludes COHS) (d)	\$29,618,383,000	\$29,618,383,000	\$0	0.00%
<i>Enrollee Premiums (expenditures)</i>				
Enrollees, individually purchased insurance	\$21,229,233,000	\$21,475,767,000	\$246,534,000	1.16%
Outside Covered California	\$4,867,955,000	\$4,916,219,000	\$48,264,000	0.99%
Through Covered California	\$16,361,278,000	\$16,559,548,000	\$198,270,000	1.21%
Enrollees, group insurance (e)	\$18,263,775,000	\$18,459,450,000	\$195,675,000	1.07%
<i>Enrollee out-of-pocket expenses</i>				
Cost-sharing for covered benefits (deductibles, copayments, etc.)	\$13,857,141,000	\$14,008,007,000	\$150,866,000	1.09%
Expenses for noncovered benefits (f) (g)	\$0	\$0	\$0	0.00%
Total Expenditures	\$146,774,787,000	\$148,045,209,000	\$1,270,422,000	0.87%

Source: California Health Benefits Review Program, 2023.

Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, and Medi-Cal.

(b) In some cases, a union or other organization. Excludes CalPERS.

(c) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.1% are state retirees, state employees, or their dependents. About one in five (22.5%) of these enrollees has a pharmacy benefit not subject to DMHC. However, CHBRP has projected an impact for those enrollees (see Appendix C).

- (d) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. In addition, CHBRP estimates that it's likely that there would also be a proportional increase of \$0 for Medi-Cal beneficiaries enrolled in COHS managed care.
 - (e) Enrollee premium expenditures include contributions by enrollees to employer (or union or other organization)-sponsored health insurance, health insurance purchased through Covered California, and any contributions to enrollment through Medi-Cal to a DMHC-regulated plan.
 - (f) 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 would be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.
 - (g) 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).
 - (h) The decrease from 0.1% at baseline to 0% postmandate is very small and mathematically undefined. It represents a complete removal of enrollees without coverage in the regulated plans.
- Key: CalPERS = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Operated Health Systems; DMHC = Department of Managed Health Care; FDA = U.S. Food and Drug Administration; GLP = glucagon-like peptide; IBT = intensive behavioral therapy.

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 SB 839, Obesity Treatment Parity Act.

Bill-Specific Analysis of SB 839, Obesity

SB 839 would require comprehensive coverage for obesity treatments, including:

- Drugs approved by the Food and Drug Administration (FDA) with an indication for chronic weight management — with coverage criteria for the drugs not being more restrictive than the FDA-approved indications;
- Bariatric surgery; and
- Intensive behavioral therapy (IBT).

SB 839 would also require that cost sharing for obesity treatments not be different or separate from treatments for other illnesses, conditions, or disorders.

The full text of SB 839 can be found in Appendix A.

Descriptions of cost sharing can be found in Appendix D.

Relevant Populations

If enacted, SB 839 would apply to the health insurance of approximately 14 million enrollees (36% of all Californians). This represents 61% of the 22.8 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law, which includes health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). If enacted, the law would apply to the health insurance of enrollees in DMHC-regulated plans and CDI-regulated policies, exempting Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Because SB 839 specifies “group and individual” plans and policies, the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans would not be subject to SB 839’s requirements.³

Analytic Approach and Key Assumptions

For this analysis, CHBRP has focused on the prescription drugs, surgeries, and behavioral therapy that seem most directly referenced in the bill language (see the *Background* section for more detail). The language of SB 839 could be interpreted as creating benefit coverage requirements for additional tests, treatments, and services that treat obesity.

For this analysis, CHBRP has made a number of assumptions.

CHBRP has assumed that plans and policies that would not have covered outpatient prescription drugs or brand-name outpatient prescription drugs would not be required to do so for prescription drugs with FDA indication for weight management. Almost all (95.6%) commercial/CalPERS enrollees in plans and policies regulated by DMHC or CDI have an outpatient pharmacy benefit regulated by DMHC or CDI that covers both generic and brand-name outpatient prescription medications.⁴ Of the remaining

² CHBRP’s authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.

³ Personal communication, W. White, California Department of Health Care Services, March 2020.

⁴ For more detail, see CHBRP’s resource, *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at http://chbrp.org/other_publications/index.php.

commercial/CalPERS enrollees, 1.2% do not have a pharmacy benefit and 3.2% have a pharmacy benefit that is not regulated by DMHC or CDI. In other words, CHBRP assumes SB 839 would have no impact for plans without a regulated pharmacy benefit except for CalPERS, which is discussed in Appendix C.

For the prescription drugs, CHBRP has assumed that on-formulary coverage with cost sharing parity for one on glucagon-like peptide 1 (GLP-1) receptor agonist⁵ and one non-GLP-1 would comply with the mandate.

CHBRP has assumed that CHBRP has assumed that SB 839's requirement for cost sharing parity would not interfere with the health savings account (HSA) qualification of a high deductible health plan (HDHP). The California Preventive Services Benefit Mandate prohibits cost sharing (including the application of any deductible) for intensive behavioral therapy for obesity.⁶ An HSA-qualified HDHP may not provide benefits for any year until the deductible for that year is satisfied, but federal law provides a safe harbor for the absence of a deductible applicable to preventive care.⁷ The list of preventive services for which application of a deductible is not required includes treatments for chronic conditions.⁸ Intensive behavioral therapy as a treatment for obesity is listed as a treatment for a chronic condition and so the cost sharing prohibition of the California preventive services benefit mandate does not interfere with HSA-qualification for the 6% of commercial/CalPERS enrollees in HSA-qualified HDHPs.⁹ CHBRP has assumed that the current prohibition on cost sharing for intensive behavioral therapy would not result in a similar prohibition for all other obesity treatments (which would interfere with HSA-qualification).

Interaction with Existing State and Federal Requirements

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

California Policy Landscape

California law and regulations

California's preventive services benefit mandate requires coverage of tests, treatments, and services with an "A" or "B" recommendations from the United States Prevention Task Force (USPSTF). IBT for weight loss is a "B" USPSTF recommendation.¹⁰

Although their benefit coverage would not be subject to SB 839's benefit mandate:

- Medi-Cal beneficiaries have coverage for glucagon-like peptide 1 (GLP-1)¹¹ and non-GLP-1 drugs with FDA indication for weight management, bariatric surgery, and IBT for weight loss.¹²

⁵ One drug, Tirzepatide (Zepbound), is a dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1

⁶ For more detail, see *Federal Recommendations and the California and Federal Preventive Services Benefit Mandates*, available at <https://www.chbrp.org/other-publications/resources>.

⁷ For more information on screening services, see Notice 2004-23, 2004-15 I.R.B. 725, available at www.irs.gov/irb/2004-15_IRB#NOT-2004-23.

For additional guidance on preventive care, see Notice 2004-50, 2004-2 C.B. 196, Q&A 26 and 27, available at www.irs.gov/irb/2004-33_IRB#NOT-2004-50; and Notice 2013-57, 2013-40 I.R.B. 293, available at IRS.gov/pub/irs-drop/n-13-57.pdf.

⁸ For information on preventive care for chronic conditions, see Notice 2019-45, 2019-32 I.R.B. 593, available at www.irs.gov/pub/irs-drop/n-19-45.pdf.

⁹ For more detail, see *Deductibles in State-Regulated Health Insurance*, available at <https://www.chbrp.org/other-publications/resources>.

¹⁰ <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/obesity-in-adults-interventions>

¹¹ One drug, Zepbound, is a dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1

¹² Personal communication, N. Johnson, DHCS, October 2023

- Californians with health insurance through Federal employment have coverage for obesity treatment that include drugs with an FDA indication for weight management, surgeries, and behavioral therapy.¹³

Similar requirements in other states

CHBRP is unaware of similar requirements in other states.

Federal Policy Landscape

Affordable Care Act

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how SB 839 may interact with requirements of the ACA as presently exist in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).^{14,15}

Essential Health Benefits

In California, nongrandfathered¹⁶ individual and small-group health insurance is generally required to cover essential health benefits (EHBs).¹⁷ In 2024, approximately 12.1% of all Californians will be enrolled in a plan or policy that must cover EHBs.¹⁸

States may require state-regulated health insurance to offer benefits that exceed EHBs.^{19,20,21} Should California do so, the state could be required to defray the cost of additionally mandated benefits for enrollees in health plans or policies purchased through Covered California, the state's health insurance marketplace. However, state benefit mandates specifying provider types, cost sharing, or other details of existing benefit coverage would not meet the definition of state benefit mandates that could exceed EHBs²²

¹³ <https://www.opm.gov/healthcare-insurance/healthcare/carriers/2023/2023-01.pdf>

¹⁴ The 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 EHBs. Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other_publications/index.php.

¹⁵ 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.

¹⁶ A grandfathered health plan is “a group health plan that was created — or an individual health insurance policy that was purchased — on or before March 23, 2010. Plans or policies may lose their ‘grandfathered’ status if they make certain significant changes that reduce benefits or increase costs to consumers.” Available at: www.healthcare.gov/glossary/grandfathered-health-plan.

¹⁷ For more detail, see CHBRP’s issue brief *California State Benefit Mandates and the Affordable Care Act’s Essential Health Benefits*, available at https://chbrp.org/other_publications/index.php.

¹⁸ See CHBRP’s resource *Sources of Health Insurance in California for 2024* and CHBRP’s issue brief *California State Benefit Mandates and the Affordable Care Act’s Essential Health Benefits*, both available at https://chbrp.org/other_publications/index.php.

¹⁹ ACA Section 1311(d)(3).

²⁰ State benefit mandates enacted on or before December 31, 2011, may be included in a state’s EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

²¹ However, as laid out in the Final Rule on EHBs U.S. Department of Health and Human Services (HHS) released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the state’s EHBs, and there would be no requirement that the state defray the costs of those state-mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.

²² Essential Health Benefits. Final Rule. A state’s health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and qualified health plan issuers would be responsible for calculating the cost that must be defrayed. Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

As the drugs, surgeries, and behavioral therapy that are the focus of this analysis are regularly covered (though the drugs may not be on formulary), it seems unlikely that SB 839 would exceed the definition of EHBs in California.

BACKGROUND ON OBESITY

SB 839 would require comprehensive coverage for obesity treatments including drugs approved by the FDA with an indication for chronic weight management, bariatric surgery, and intensive behavioral therapy. SB 839 would also require that coverage criteria for the drugs are not more restrictive than the FDA-approved indications. This background section provides information related to obesity to provide context for the consideration of the *Medical Effectiveness*; *Benefit Coverage, Utilization, and Cost Impacts*; and *Public Health Impacts* sections.

Obesity

Obesity is a chronic health condition characterized by an increase in the size and amount of fat cells in the body (NIH, 2022). Healthcare providers screen for obesity by calculating patients' body mass index (BMI), which takes into account an individual's height and weight. Individuals with a body mass index of 25 or higher are categorized as overweight and those with a BMI of 30 or higher are categorized as obese. The obese category can be further delineated into three categories (CDC, 2022):

- Class 1: BMI of 30 to <35
- Class 2: BMI of 35 to <40
- Class 3: BMI of 40 or higher

There are many health consequences of obesity such as an increased risk of heart disease, diabetes, and certain cancers, as well as reduced life expectancy (NIH, 2022). Causes of obesity are multi-faceted and can include lifestyle habits, environment, socioeconomic factors, and individual characteristics such as genetics and metabolism (Lee et al., 2019).

Obesity Prevalence in California

Table 2 describes the prevalence of overweight and obesity by age. Prevalence of overweight and obesity is defined differently for children (BMI between the 85th and 95th percentile; BMI in the 95th percentile or above) and adults (BMI 25 to <30; BMI \geq 30). Obesity treatments are recommended for individuals with obesity, as well as for some who are overweight (i.e., individuals with BMI \geq 27 to <30) who have comorbidities such as cardiovascular disease, type 2 diabetes, and hypertension (Jensen et al., 2014). Unadjusted data in Table 2 show patterns in overweight and obesity by age, with rates increasing with age. Overall, it is estimated that 10.9% of adolescents aged 13 to 17 and 26.7% of adults aged 18 to 64 with private health insurance in California have BMIs that would categorize them as having obesity. In addition, it is estimated that an additional 13% of overweight Californians with BMIs \geq 27 and <30 with health insurance subject to SB 839 would also be eligible for treatment due to the presence of comorbidities.²³ This translates into 3.5 million total Californians eligible for obesity treatments enrolled in health insurance subject to SB 839 (Table 1).

²³ A CHBRP analysis of California Health Interview Survey Data (CHIS) 2022 data found that approximately 13% of 18- to 64-year-olds with a BMI of 27 to <30 enrolled in private health insurance plans had been diagnosed with either diabetes, heart disease, or hypertension in their lifetime.

Table 2. Prevalence of Overweight and Obesity in California’s Privately Insured Population by Age, 2022

Age	Overweight ^a (BMI 25.0 to <30)	Obese (BMI ≥30)
13-17 ^b	18.8%	10.9%
18-24	22.8%	15.5%
25-39	32.6%	24.7%
40-64	36.8%	30.3%
18-64 ^c	33.7%	26.7%

Source: California Health Benefits Review Program, 2023, analysis of the California Health Interview Survey Data. Analysis limited to respondents with employment-based and privately purchased health insurance.

Note: (a) A proportion of those who have BMIs between 27 and 29.9 would also be eligible for obesity treatments if they have additional comorbidities. This has been estimated to be 13% of the overweight population.

(b) Overweight for children under age 18 is defined as having a BMI between the 85th and 95th percentile while obesity is defined as having a BMI in the 95th percentile or above (NIH, 2022). Estimates for teens (aged 13-17) are presented because the data source did not include information on obesity rates for children aged 0 to 12.

(c) In addition, rates for adults >65 are not presented because the vast majority of that population is enrolled in Medicare and thus not enrolled in health insurance subject to SB 839.

Key: BMI = body mass index.

Treatments for Obesity Weight Management

There are three types of treatments for obesity that are relevant to SB 839: drugs approved by the FDA with an indication for chronic weight management, bariatric surgery, and intensive behavioral therapy (IBT) (Cornier, 2022). A description and summary of clinical practice guidelines for each type of treatment is described in more detail below.

Drugs with FDA Indication for Weight Management

Specific to SB 839, there are eight different drugs with FDA indication for weight management as of November 9, 2023. The drug name, brand name, year of FDA approval, mode of administration, and population are presented in Table 3 below. There are two main types of drugs approved by the FDA with an indication for chronic weight management: glucagon-like peptide 1 (GLP-1) receptor agonists (RA) and non-GLP-1s. The mechanism of action of GLP-1RA therapy centers on activation of GLP-1 receptors in the gut leading to delayed gastric emptying and in the hypothalamus of the central nervous system affecting satiety centers (Ard et al., 2021). Non-GLP-1 RA therapies involve a multitude of pharmacologic mechanisms of action. For example, Orlistat functions by reducing intestinal absorption of fat via inhibition of pancreatic lipase (Aaseth et al., 2021). The combination drug containing bupropion/naltrexone includes bupropion, which is a norepinephrine and dopamine reuptake inhibitor that stimulates pro-opiomelanocortin, a neuropeptide linked to appetite suppression (Aaseth et al., 2021); naltrexone targets appetite-stimulating effects of endorphins to address food cravings (Aaseth et al., 2021). Phentermine is an amphetamine stimulant analogue and is also present in a combination medication with the anti-epileptic topiramate. The mechanism of action for topiramate is thought to relate to mitigation in energetic efficiency leading to reduction in fat deposition (Verrotti et al., 2011).

Table 3. FDA-Approved Drugs for Weight Management Relevant to SB 839, As of November 2023

Drug (Brand Name)	FDA Approval Year	Mode of Administration /Dosage	Population Approved/ Indicated For
GLP-1			
Liraglutide (Saxenda)	2014 adults; 2020 aged 12+ years	Daily subcutaneous.	Adults with BMI of ≥ 30 kg/m ² or ≥ 27 kg/m ² with comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia). 12+ years with body weight above 60 kg and an initial BMI corresponding to 30 kg/m ² for adults by international cut-offs.
Semaglutide (Wegovy)	2021 adults; 2023 aged 12+	Weekly subcutaneous, gradually increase dose every four weeks.	Adults with BMI ≥ 30 kg/m ² or ≥ 27 kg/m ² in the presence of comorbid condition. 12+ years with BMI at the 95th percentile or greater standardized for age and sex.
Tirzepatide (Zepbound)(a)	2023	Weekly subcutaneous	Adults with BMI ≥ 30 kg/m ² or ≥ 27 kg/m ² with comorbid condition.
Non GLP-1			
Bupropion/ Naltrexone (Contrave)	2014	Daily orally. Dose is increased weekly until target dosage of two tablets twice daily.	Adults with an initial BMI of ≥ 30 kg/m ² or ≥ 27 kg/m ² with weight-related comorbid condition.
Orlistat (Xenical)	1999	Daily orally	Adults with BMI of ≥ 30 kg/m ² or a BMI of ≥ 27 kg/m ² in the presence of other comorbidities.
Phentermine/ Topiramate (Qsymia)	2012	Daily orally	Adults with BMI of ≥ 30 kg/m ² or ≥ 27 kg/m ² with weight-related comorbid condition. Pediatric patients aged 12 years and older with BMI in the 95th percentile or greater.
Setmelanotide (Imcivree)	2020	Daily subcutaneous	Age 6+ years for people living with Bardet-Biedl syndrome (BBS), or POMC, PCSK1, or LEPR deficiency.
Phentermine (Adipex-P, Lomaira)	1959	Daily orally; approved by the FDA for short-term use (three months)	Age 16+ years with BMI of 30 kg/m ² or greater or 27 kg/m ² or greater) in the presence of at least one weight-related comorbid condition.

Source: California Health Benefits Review Program, 2023; FDA, 2023.

Note: (a) Tirzepatide (Zepbound) is a dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1.

Key: BMI = body mass index; GLP = glucagon-like peptide-1 (GLP-1); FDA = U.S. Food and Drug Administration.

Clinical practice guidelines for adults

In 2018, the United States Preventive Services Task Force (USPSTF) recommended that clinicians promote behavioral interventions as the primary intervention for weight management in adults because it is unclear whether results from randomized controlled trials (RCTs) of FDA-approved weight management drugs that were on the market in 2018 (liraglutide, bupropion/naltrexone, orlistat, and

phentermine/topiramate)²⁴ are applicable to the general U.S. primary care population due to high attrition rates and highly selective inclusion criteria required to participate in the trials (e.g., proof of adherence to medication schedules and meeting weight loss goals prior to enrollment in trials) (USPSTF, 2018).

Multiple additional studies of weight management drugs have been published since the USPSTF systematic review was published in 2018 recommending behavioral interventions as the first line of therapy.

Guidance on weight management drugs for children and adolescents

In 2023, the American Academy of Pediatrics (AAP) issued a clinical practice guideline regarding weight management drugs for children and adolescents with obesity that states “Pediatricians and other pediatric health care providers should offer adolescents 12 years and older with obesity (BMI ≥ 95th percentile) weight loss pharmacotherapy, according to medication indications, risks, and benefits, as an adjunct to health behavior and lifestyle treatment” (Hampel et al., 2023).

Bariatric Surgery

There are five different surgeries used to treat obesity relevant to SB 839. The surgery type, procedure description, and mechanism of action and intended clinical effect are presented in Table 4 below.

Table 4. Bariatric Surgeries Relevant to SB 839

Surgery Type	Procedure Description	Mechanism of Action (i.e., How it Works)
Sleeve Gastrectomy	Removes approximately 80% of the stomach.	Reduces the stomach size, limiting food intake and removes the portion of the stomach that produces the "hunger hormone."
Roux-en-Y Gastric Bypass (RYGB)	Stomach is divided into a smaller pouch (size of an egg) and the small intestine is rerouted.	Reduces stomach size, limits food intake and decreases food absorption in the small intestine.
Adjustable Gastric Band (AGB)	Silicone band placed around the top of the stomach.	Adjusted band size may impact the feeling of fullness. The band can be adjusted or removed if needed.
Biliopancreatic Diversion with Duodenal Switch (BPD/DS)	A tube-shaped stomach pouch is created, bypassing most of the small intestine.	Reduces stomach size, limiting food intake; 75% of the small intestine is bypassed, which can impact intestinal hormones and hunger.
Single Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy (SADI-S)	Similar to BPD-DS, with a simpler and faster procedure.	Creates a smaller tube-shaped stomach and connects it to the latter part of the small intestine.

Source: Eisenberg et al., 2023.

²⁴ These RCTs compared liraglutide, bupropion/naltrexone, orlistat, and phentermine/topiramate to a placebo or to a placebo and another weight management drug.

Guidance on bariatric surgery for adults

The American Society for Metabolic and Bariatric Surgery/International Federation for the Surgery of Obesity and Metabolic Disorders (ASMBS/IFSO) Guidelines published in 2022 recommend metabolic and bariatric surgery for individuals with a BMI of 35 or more “regardless of presence, absence, or severity of obesity-related conditions” and that it be considered for people with a BMI of 30 to 34.9 and metabolic disease (Eisenberg et al., 2023).

Guidance on bariatric surgery for children and adolescents

In 2023, the AAP issued a clinical practice guideline regarding bariatric surgery for children and adolescents with obesity that states “Pediatricians and other pediatric health care providers should offer referral for adolescents 13 years and older with severe obesity (BMI \geq 120% of the 95th percentile for age and sex) for evaluation for metabolic and bariatric surgery to local or regional comprehensive multidisciplinary pediatric metabolic and bariatric surgery centers” (Hampl et al., 2023).

Intensive Behavioral Therapy (IBT)

The USPSTF defines intensive behavioral therapy (IBT) for obesity as a particular form of intensive, multicomponent behavioral intervention that typically lasts for 1 to 2 years, encompasses 12 or more sessions during the first year, and provides patients with tools to support weight loss and maintenance of weight loss (e.g., food scales, pedometers) (USPSTF, 2018). Many IBTs are modeled after the Diabetes Prevention Program (USPSTF, 2018). This program includes weekly group meetings led by a trained lifestyle coach for 6 months, followed by 6 months of meeting once or twice a month. The Diabetes Prevention Program curriculum is offered through a variety of organizations across the United States that are part of the Centers for Disease Control and Prevention’s (CDC’s) national registry of recognized organizations (CDC, 2023).

Guidance on intensive behavioral therapy for adults

In 2018, the USPSTF recommended that “clinicians offer or refer adults with a body mass index of 30 or higher to intensive, multicomponent behavioral interventions. The USPSTF (2018) concluded that effective behavioral intervention for weight loss has the following characteristics:

- Designed to help participants achieve or maintain a \geq 5% weight loss through a combination of dietary changes and increased physical activity;
- Lasted for 1 to 2 years, and, in the majority of cases, had \geq 12 sessions in the first year;
- Focused on problem solving to identify barriers to weight loss, self-monitoring of weight, peer support, and relapse prevention; and
- Provided tools to support weight loss or weight loss maintenance (e.g., pedometers, food scales, or exercise videos).

Guidance on intensive behavioral therapy for children and adolescents

In 2023, the AAP issued a clinical practice guideline regarding IBT²⁵ for children and adolescents with obesity that states “Pediatricians and other pediatric health care providers should provide or refer children 6 years and older and may provide or refer children 2 through 5 years of age with overweight (BMI \geq 85th percentile to $<$ 95th percentile) and obesity (BMI \geq 95th percentile) to health behavior and lifestyle treatment (Hampl et al., 2023).

²⁵ The American Academy of Pediatrics uses the terminology “intensive health behavior treatment.”

Disparities²⁶ in Obesity Prevalence and Treatment

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 drivers or systemic factors exist, CHBRP describes relevant literature. CHBRP found literature identifying disparities by race/ethnicity, income, and geography.

Table 5 demonstrates patterns in overweight and obesity by key demographics among California adults. Obesity rates are lowest among those with the highest incomes and educational attainment. Rates of obesity vary in California by race and ethnicity with Asian adults reporting the lowest rates of obesity (13%) followed by White adults (23.7%), with American Indian/Alaska Native adults (40.4%), Black adults (39.1%), and Latino adults (39.4%) all reporting the highest rates. Finally, adults residing in urban locations reported lower rates of obesity compared to adults residing in rural locations.

Table 5. Prevalence of Overweight and Obesity among California Adults (18-64) by Key Demographic Characteristics, 2022

Demographic Characteristic	Overweight ^a (BMI 25.0- <30)	Obese (BMI ≥30)
Race/Ethnicity		
American Indian/Alaska Native	30.7%	40.4%
Asian	28.3%	13.0%
Black	33.5%	39.1%
Latino	35.8%	39.4%
White	34.5%	23.7%
Gender²⁷		
Female	27.5%	26.4%
Male	39.9%	26.9%
Transgender or gender non-conforming	35.6%	21.6%
Sexual Orientation		
Straight/Heterosexual	34.1%	26.4%
Gay, lesbian, bisexual, asexual	31.7%	28.6%
Federal Poverty Level		
0-99%	35.5%	30.4%
100-199%	29.5%	29.7%
200-299%	35.0%	29.0%
300%+	33.8%	25.9%
Location of Residence		
Urban	32.8%	25.2%
Rural	36.4%	31.0%

²⁶ 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).

²⁷ CHBRP uses the NIH distinction between “sex” and “gender”: “Sex” refers to biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles. ‘Gender’ refers to socially constructed and enacted roles and behaviors which occur in a historical and cultural context and vary across societies and over time.” (NIH, 2019)

Education		
<High School	39.8%	37.9%
High School Graduate	32.5%	33.2%
Some College/Vocational School	32.4%	33.2%
College Graduate	33.8%	21.6%

Source: California Health Benefits Review Program, 2023, analysis of the California Health Interview Survey Data.

Note: (a) A proportion of those who have BMIs between 27 and 29.9 would also be eligible for obesity treatments if they have additional comorbidities. This has been estimated to be 13% of the overweight population.

(b) overweight for children under age 18 is defined as having a BMI between the 85th and 95th percentile while obesity is defined as having a BMI in the 95th percentile or above (NIH, 2022).

Key: BMI = body mass index.

Barriers to Accessing Obesity Treatments

It is estimated that only 10% of those with obesity seek help from a professional to lose weight, with approximately 6.4% consulting a non-physician health professional (dietician, personal trainer, etc.) and 3.6% consulting a physician (Stokes et al., 2018). While not everyone with obesity is diagnosed and attempts to seek treatments, among those who do, there are still many factors that serve as barriers to accessing treatments such as:

- **Stigma:** People with obesity often face stigma and discrimination, which make them less likely to engage with the health care system. In addition, physicians may negatively stereotype patients with higher BMIs resulting in lower likelihood of recommending treatments (Washington et al., 2023).
- **Racism and discrimination:** People of color have higher rates of obesity. This is in part because they are more likely to live in neighborhoods with obesogenic food environments (Washington et al., 2023). Black and Latino adults are also more likely to develop an obesity-related disease such as high blood pressure, heart attack, and stroke (Washington et al., 2023). In addition to there being disparities in obesity rates by race and ethnicity, there are also disparities in access to anti-obesity treatments and outcomes. Specifically, it was found that Black and Hispanic adults with obesity were more likely to have financial barriers to accessing GLP-1s compared to White adults (Lu et al., 2022). Furthermore, people of color who have obesity are less likely to be assessed for and diagnosed with obesity and offered treatments for obesity (Washington et al., 2023).
- **Location:** Rates of obesity are higher among rural adults (31.0%) compared to urban adults (25.2%). In addition, the concentration of obesity medicine specialists in more urban and suburban areas makes it more difficult for obese adults in rural areas to access care. People living in rural areas are more likely to face challenges in finding a health care provider that specializes in obesity medicine and are likely to live further away from major surgery centers. It is estimated that the travel time to an obesity medicine specialist is almost five times as long for adults in rural areas compared to adults in urban areas (43 vs. 9 minutes) (Washington et al., 2023).
- **Lack of awareness:** Approximately half of overweight or obese adults reported having either no (23%) or just a little (24%) awareness of drugs to manage obesity (KFF, 2023). This lack of awareness may impact their chances of seeking treatment.
- **Expense:** The high cost of some obesity treatments can make them inaccessible for patients with lower incomes (Levi et al., 2023). As shown in Table 5, those in the highest income group ($\geq 300\%$ FPL) have much lower rates of obesity than those in the lower income groups. This is in part because people with lower incomes are more likely to find it challenging to address lifestyle factors contributing to obesity such as a lack of time and money to dedicate to healthy meal preparation and exercise, a higher likelihood of living in a built environment that is not conducive to eating healthy and exercising, and a higher likelihood of experiencing stress (Washington et al., 2023).

- **Supply Shortage:** Currently there are supply chain issues that prevent everyone who wants GLP-1 drugs from getting them. This analysis assumes that these issues would be solved by the time the mandate goes into effect (see *Benefit Coverage, Utilization, and Cost Impacts* section).

Societal Impact of Obesity in the United States and California

Treatment of obesity-related diseases places a large economic burden on the health care system. In a report by the Milken Institute, researchers estimated that the total economic costs attributed to overweight and obesity in the United States exceeded \$1.72 trillion — comprised of \$480.7 billion in direct health care costs due to diseases caused by overweight and obesity and an additional \$1.24 trillion in indirect costs due to lost productivity in 2016 (Waters and Graf, 2018). Translated into 2023 dollars,²⁸ the total direct and indirect costs related to overweight and obesity equates to \$2.1 trillion per year in the United States.

When evaluating direct medical care costs attributed to obesity in the United States, Cawley et al. (2021a) found that the annual average medical expenditures for adults with obesity (\$5,010) were approximately twice as high as those incurred by adults with normal weight (\$2,504). In addition, obesity increased costs within every level of medical care (i.e., inpatient, outpatient, and medications). Furthermore, Cawley et al. (2021a) found that as the class of obesity increased (Class 1, 2, and 3), so did the amount of annual medical expenditures. Relative to those with normal weight, additional medical expenditures increased by 68.4% (or \$1,713) among those with class 1 obesity, by 120% (or \$3,005) among those with class 2 obesity, and by 233.6% (or \$5,850) among those with class 3 obesity, respectively.

Within California, Cawley et al. (2021a) estimated the total annual medical expenditure related to adult obesity (i.e., BMI ≥ 30). In 2016, the total annual medical care expenditures (i.e., direct costs comprised of public and private health insurance expenditures as well as out-of-pocket costs) due to obesity in California was equal to \$5.3 billion (Cawley et al., 2021a). Translated into 2023 dollars, the total medical expenditures attributed to obesity in California is equal to \$6.8 billion.

²⁸ Translated into 2023 dollars using <https://www.usinflationcalculator.com/>

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, SB 839 would mandate comprehensive coverage for obesity treatments, including coverage for FDA-approved weight management drugs, bariatric surgery, and intensive behavioral therapy (IBT) for weight loss. Additional information on obesity and treatments is included in the *Background* section. The medical effectiveness review summarizes findings from evidence²⁹ regarding the effectiveness of weight management drugs, bariatric surgery, and IBT for weight loss.

Research Approach and Methods

Studies of the effectiveness of FDA-approved weight management drugs, bariatric surgery, and IBT for weight loss were identified through searches of PubMed, the Cochrane Library, Web of Science, the Cumulative Index of Nursing and Allied Health Literature (CINAHL), and PsycINFO. 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 National Institute for Health and Clinical Excellence (NICE), U.S. Preventive Services Task Force (USPSTF), World Health Organization (WHO), 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 1,655 articles found in the literature search, 176 were reviewed for potential inclusion in this report on SB 839, and a total of 50 studies were included in the medical effectiveness review for this report. Articles were eliminated because they did not address the treatments for which SB 839 would require coverage, assessed drugs that were not FDA-approved for weight management, were of poor quality, did not report findings from clinical research studies, or did not report weight-related outcomes. 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.³⁰ Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 90-day timeframe for this report.

Key Questions

1. In adults and children/adolescents, what is the effect of FDA-approved weight management drugs, bariatric surgery, and IBT for weight loss on the incidence of adult and childhood obesity compared with no intervention?
2. What is the effect of FDA-approved weight management drugs, bariatric surgery, and IBT for weight loss on health outcomes associated with obesity (including associated use of healthcare services)?

²⁹ Much of the discussion in this section is focused on reviews of available literature. However, as noted in the section on Implementing the Hierarchy of Evidence in the *Medical Effectiveness Analysis and Research Approach* document (posted at http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php), in the absence of peer-reviewed literature on well-designed randomized controlled trials (RCTs) that are fully applicable to a bill, CHBRP's hierarchy of evidence allows for the inclusion of other evidence.

³⁰ 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 http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

Methodological Considerations

CHBRP's literature review of treatments for obesity focused on the FDA-approved weight management drugs, bariatric surgery, and IBT for weight loss. CHBRP's review of literature on behavioral health interventions for weight loss was limited to IBT because SB 839 only requires coverage for IBT and does not address coverage for less intensive behavioral interventions for weight loss. CHBRP limited its review of literature on weight management drugs to drugs that the FDA has approved for weight management because SB 839 would only require health plans and policies to cover drugs that are specifically FDA-approved for weight management.

Outcomes Assessed

Primary outcomes assessed included: change in body weight; percent excessive weight loss (%EWL); weight reduction of 5%³¹, 10%, or 15%; body mass index (BMI); and mean BMI change. Health outcomes associated with obesity included: diabetes risk; glycated hemoglobin (A1C); systolic blood pressure (SBP); diastolic blood pressure (DBP); waist circumference; functional quality of life. CHBRP also reviewed literature on harms of FDA-approved weight management drugs and complications from bariatric surgery.

Study Findings

This following section summarizes CHBRP's findings regarding the strength of evidence for the effectiveness of FDA-approved weight management drugs, bariatric surgery, and IBT for weight loss. 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.

³¹ The U.S. Food and Drug Administration considers a weight loss of 5% as clinically important (LeBlanc et al., 2018).

FDA-Approved Weight Management Drugs

CHBRP identified multiple systematic reviews and meta-analyses that examined the effectiveness of FDA-approved weight management drugs. Most of the evidence comes from the Institute for Clinical and Economic Review (ICER) report (Atlas et al., 2022), which presents findings from a systematic review and meta-analysis of 37 studies of four drugs approved by the FDA: liraglutide (Saxenda®, Novo Nordisk, 2014), semaglutide (Wegovy®, Novo Nordisk, 2021), bupropion/naltrexone (Contrave®, Currax Pharmaceuticals, 2014), and phentermine/topiramate (Qsymia®, Vivus, 2012). Liraglutide and semaglutide are glucagon-like peptide-1 (GLP-1)³² receptor agonists that are also approved for treating diabetes mellitus and are given by subcutaneous injection, whereas bupropion/naltrexone and phentermine/topiramate are combination oral agents that work via other mechanisms. Most of the evidence regarding the effectiveness of these drugs comes from Phase III randomized controlled trials (RCTs) conducted prior to FDA approval. These RCTs compared the weight management drugs to placebo among patients who received a variety of lifestyle interventions. As a result, the studies assessed the additive benefit of the drugs in addition to lifestyle interventions. A few studies incorporated intensive lifestyle interventions that included IBT or structured meal programs.

Effect of FDA-Approved Weight Management Drugs Compared to Placebo on Weight Management Outcomes

Glucagon-like peptide-1 (GLP-1) receptor agonists

Liraglutide 3.0 mg (Saxenda)

Effectiveness of liraglutide on weight management outcomes in adults: Four SCALE Phase III RCTs (6,632 subjects; Atlas et al., 2022) reported that liraglutide 3.0 mg was associated with significant weight reduction for patients with overweight or obesity, regardless of whether they have diabetes, compared to placebo. Three RCTs (Maintenance, Obesity and Pre-Diabetes, and IBT trials) reported that participants in the liraglutide group consistently achieved significantly greater percent weight loss at 1 year (-6.2%, -8%, and -7.4%, respectively) versus placebo (-0.2%, -2.6%, and -4%, respectively). Similarly, a significantly greater proportion of participants in the liraglutide group achieved $\geq 5\%$ weight loss and $\geq 10\%$ weight loss. In the SCALE Type 2 Diabetes study,³³ participants lost significantly more bodyweight (6.4 kg) with liraglutide compared to placebo (6.0% versus 2.0%). Significantly more participants in this study who took liraglutide achieved weight loss of 5% and 10% than participants who received a placebo (54.3% versus 21.4% and 25.2% versus 6.7%, respectively). Network meta-analyses of the SCALE trials reported that participants who received liraglutide had a larger percentage weight loss at 1 year than participants who received a placebo among both participants who had obesity without diabetes (estimated absolute difference in percentage weight loss -5.0) and participants who had obesity and diabetes (estimated absolute differences in percentage weight loss -3.7).

In a systematic review and meta-analysis of 143 RCTs (49,810 subjects), Shi et al. (2022) compared different weight management drugs plus lifestyle modification with lifestyle modification alone in adults with overweight or obesity. At 1-year follow-up, the mean difference in the percentage of body weight lost for participants who received liraglutide and participants who received placebo was statistically significant (-4.68%). A greater proportion of liraglutide participants reduced their bodyweight by $\geq 5\%$ and $\geq 10\%$ compared to participants who received lifestyle modification alone.

Effectiveness of liraglutide on weight management outcomes in adolescents: A meta-analysis (Cornejo-Estrada et al., 2023; 2 RCTs; 296 subjects received liraglutide) reported that there was no statistically significant difference in weight loss or reduction in BMI between adolescents who received liraglutide and adolescents who received a placebo.

³² One drug, Zepbound, is a dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1

³³ Participants in SCALE (Type 2 Diabetes) study included adults aged ≥ 18 with overweight or obesity (BMI ≥ 27 kg/m²) with a diagnosis of type 2 diabetes mellitus treated with diet and exercise alone or one to three oral hypoglycemic medications.

Semaglutide 2.4 mg (Wegovy)

Effectiveness of semaglutide on weight management outcomes in adults: In adults with overweight or obesity, the Semaglutide Treatment Effect in People with Obesity (STEP)³⁴ 1-6 RCTs (5,388 subjects) reported that use of semaglutide was associated with clinically meaningful decreases in bodyweight compared with placebo (Atlas et al., 2022). In the STEP 1 and STEP 5 RCTs, participants in the semaglutide 2.4 mg arm showed significantly greater percent weight loss at 68 weeks (-14.9% and -15.8%, respectively) than placebo (-2.4% and -3.3%, respectively). Additionally, in both trials, a significantly greater proportion of participants who received semaglutide achieved $\geq 5\%$ weight loss, $\geq 10\%$ weight loss, and $\geq 15\%$ weight loss compared to participants in the placebo arm. Davies et al. (2021; 1,210 subjects) reported that participants in the STEP 2 RCT, who were comprised of adults with BMI of 27 kg/m² who had diabetes but no renal disease, who received semaglutide 2.4 mg achieved significantly greater percent weight loss at 1 year versus participants who received a lower dose of semaglutide (1.0 mg) or placebo (-9.6% versus -6.99% versus -3.4%, respectively). At week 68, significantly more participants who received semaglutide 2.4 mg achieved weight reductions of $\geq 5\%$ compared to participants who received a placebo. Network meta-analyses of the STEP trials reported that participants who received semaglutide had a larger percentage weight loss at 1 year than participants who received a placebo among both participants who had obesity without diabetes (estimated absolute difference in percentage weight loss -13.7) and participants who had obesity and diabetes (estimated absolute differences in percentage weight loss -7.6).

The systematic review and meta-analysis by Shi et al. (2022) reported that there was a statistically significant change of -11.41% in percentage bodyweight among participants who received semaglutide and lifestyle modification. A greater proportion of participants who received semaglutide plus lifestyle modification reduced their bodyweight by $\geq 5\%$ and $\geq 10\%$ compared to participants who received lifestyle modification alone.

Trials that examine weight management outcomes after semaglutide drug withdrawal: Two trials examined the effect of continued weekly subcutaneous semaglutide compared to drug withdrawal (placebo) on weight management maintenance in adults who were overweight or obese at the beginning of the RCT. In the STEP 4 RCT (Rubino et al., 2021; 902 subjects), all subjects received semaglutide 2.4 mg for the first 20 weeks of the study, after which they were randomly assigned to receive either semaglutide or placebo for the remaining 48 weeks. At 68 weeks, subjects who continued to take semaglutide after randomization lost significantly more bodyweight, whereas subjects who switched to placebo regained weight after discontinuing semaglutide. In the STEP 1 trial extension (Wilding et al., 2022; 327 subjects), all subjects in the group that received semaglutide 2.4 mg for the first 68 weeks had a mean weight loss of 17.3% versus 2.0% for those who received a placebo during weeks 21 to 68. Following treatment withdrawal at the end of week 68, participants that received weekly semaglutide through week 68 regained 11.6% of lost weight by week 120. Participants who received semaglutide then placebo after 68 weeks attained total weight loss of 5.6% between weeks 0 and 120, and participants who received placebo after 20 weeks achieved total weight loss of 0.1% during this time period.

Effectiveness of semaglutide on weight management outcomes in adolescents: The STEP TEENS RCT (Weghuber et al., 2022; 201 subjects) that compared semaglutide 2.4 mg to placebo for adolescents aged 12 to 18 years with overweight or obesity and at least one weight-related coexisting condition, reported that at week 68, participants who received semaglutide had a greater reduction in mean body weight than participants who received a placebo. Additionally, more participants in the semaglutide group had weight loss of $\geq 5\%$ compared to participants in the placebo group (73.0% versus 18.0%).

In a post hoc analysis of this trial, Kelly et al. (2023) reported that semaglutide 2.4 mg significantly reduced BMI in teens. Significantly more participants receiving semaglutide achieved weight reduction resulting in reclassification to a normal-weight or overweight BMI category than participants who received a placebo (44.9% versus 12.1%). Additionally, the percentage of participants receiving semaglutide who

³⁴ These trials included standard diet and exercise counseling in both intervention and placebo treatment groups.

were in obesity class III (BMI of 40 or higher) decreased (37.3% to 13.6%) at 68-week follow-up, whereas the percentage of participants in obesity class III increased among participants who received a placebo.

Tirzepatide (Zepbound)

Effectiveness of tirzepatide on weight management outcomes in adults: A phase 3 double-blind RCT of adults with overweight or obesity without diabetes (SURMOUNT-1; 2,539 subjects) compared weekly tirzepatide 5 mg, 10 mg, and 15 mg plus lifestyle counseling sessions with placebo plus lifestyle counseling sessions for 72 weeks (Jastreboff et al., 2022). The estimated differences in percentage change in body weight between tirzepatide and placebo were -11.9% for 5 mg, -16.4% for 10 mg, and -17.8% for 15 mg. The estimated differences in change in waist circumference between tirzepatide and placebo were -10.1 cm for 5 mg, -13.8 cm for 10 mg, and -14.5 for 15 mg. The proportion of subjects with $\geq 5\%$ weight loss was 85.1% with 5 mg, 88.9% with 10 mg, 90.9% with 15 mg, and 34.5% with placebo. The proportion of subjects with $\geq 20\%$ weight loss was 30.0% with 5 mg, 50.1% with 10 mg, 56.7% with 15 mg, and 3.1% with placebo. All differences between weight management outcomes in the tirzepatide and placebo groups were statistically significant.

Garvey et al. (2023) compared weekly tirzepatide 10 mg and 15 mg plus lifestyle counseling sessions versus placebo plus lifestyle counseling sessions in a phase 3 double-blind RCT involving adults with BMI ≥ 27 kg/m² and type 2 diabetes (SURMOUNT-2; 938 subjects). Tirzepatide 10 mg and 15 mg were associated with better weight loss outcomes compared to placebo. The estimated differences for tirzepatide 10 mg versus placebo were -9.6% (-9.7 kg) for change in bodyweight, -7.4 cm for change in waist circumference, and -3.5 kg/m² for mean change in BMI. The estimated differences for tirzepatide 15 mg versus placebo were -11.6% (-11.6 kg) for change in body weight, -9.8 cm for change in waist circumference, and -4.2 kg/m² for change in BMI. Greater proportions of subjects who received tirzepatide achieved $\geq 5\%$ weight loss than subject who received placebo (79.0% with tirzepatide 10 mg, 83.0% with tirzepatide 15 mg, and 32.0% with placebo).

Effectiveness of tirzepatide on weight management outcomes in adolescents: Tirzepatide is not approved for use in adolescents.

Non GLP-1 weight management drugs

Bupropion/naltrexone (Contrave)

Effectiveness of bupropion/naltrexone on weight management outcomes in adults: All RCTs of bupropion/naltrexone include elements of lifestyle interventions. Four phase III RCTs, the Contrave Obesity Research studies (COR-I, COR-II, COR-BMOD, and COR Diabetes; 4,536 patients across all trials) showed statistically significant and clinically meaningful weight loss following up to 52 weeks of treatment with bupropion/naltrexone plus lifestyle intervention versus placebo plus lifestyle intervention in patients with overweight or obesity (Atlas et al., 2022).³⁵ The RCTs found that participants who received bupropion/naltrexone plus a lifestyle intervention achieved greater weight loss at year one and that a higher percentage of them lost $\geq 5\%$ and $\geq 10\%$ of their weight compared to participants who only received a lifestyle intervention. The average weight loss for bupropion/naltrexone subjects from baseline across the studies was approximately 11 to 22 pounds. In two RCTs (Atlas et al., 2022), waist circumference was statistically significant reduced at 56 weeks after treatment with bupropion/naltrexone plus lifestyle intervention compared to lifestyle intervention alone (COR-I, COR-BMOD). Findings from network meta-analyses indicate that bupropion/naltrexone is associated with greater weight loss than placebo for both people who only have obesity (without diabetes) and people who have both obesity and diabetes (Atlas et al., 2022).

³⁵ COR-BMOD utilized more intensive lifestyle modification counseling by exercise specialists, dietitians, and psychologists over 28 sessions. Interventions included strategically planned hypocaloric diets, calorie counting, maintaining food diaries, and gradual titration of exercise requirements (Atlas et al., 2022).

The Shi et al. (2022) systematic review and meta-analysis, found a statistically significant change of -4.11% in percentage bodyweight between baseline and 1 year for bupropion/naltrexone plus lifestyle intervention. A greater proportion of participants in the bupropion/naltrexone group reduced their bodyweight by $\geq 5\%$ than participants in the lifestyle intervention alone group.

Effectiveness of bupropion/naltrexone on weight management outcomes in children and adolescents: Bupropion/naltrexone is not approved for use in children or adolescents.

Orlistat (Xenical)

Effectiveness of orlistat on weight management outcomes in adults: The systematic review by LeBlanc et al. (2018) reported that participants who received orlistat (either 60 mg or 120 mg) had greater weight loss than participants who received a placebo. At 12 months, the between-group difference in mean weight change was -2.94 kg for orlistat 60 mg (one trial) and -3.80 kg to -1.00 kg for orlistat 120 mg (seven trials). The trial of orlistat 60 mg (one trial) concluded that the impact of orlistat on mean weight change persisted at 24 months. All differences were statistically significant. Participants who received orlistat 60 mg or 120 mg were also more likely to lose $\geq 5\%$ of their body weight than participants in the placebo groups at both 12 months and 24 months follow-up.

In the systematic review and network meta-analysis by Shi et al. (2022), there was a statistically significant change of -3.16% in percentage bodyweight between baseline and 1 year for orlistat plus lifestyle modification. A greater proportion of orlistat participants reduced their bodyweight by $\geq 5\%$ and $\geq 10\%$ than lifestyle modification alone participants.

Effectiveness of orlistat on weight management outcomes in children and adolescents: In a systematic review of weight management interventions in children and adolescents, O'Connor et al. (2017) examined three studies (779 subjects) that compared thrice-daily orlistat 120 mg with a placebo pill over 6 to 12 months. Mean change in BMI was greater in the intervention groups than the control groups for all three studies with between-group differences ranging from -0.94 to -0.50. The difference was only statistically significant for two of the studies. Mean change in absolute weight ranged from -12 lbs. to 1 lb. in the intervention groups and -4 lbs. to 7 lbs. in the control groups.

Nikniaz et al., 2023 (6 studies; 695 subjects), conducted a systematic review and meta-analysis on the effects of thrice-daily orlistat 120 mg in children and adolescents with obesity. Four RCTs (six reports) were included in the meta-analysis. Nikniaz et al. (2023) reported that compared to the control groups,³⁶ orlistat was associated with greater reduction in waist circumference but there was no statistically significant difference in body weight or BMI. An additional two quasi-experimental (before-after) studies were included in the review — both reported that taking orlistat for three months was associated with a significant reduction in body weight, waist circumference, and BMI.

Phentermine/topiramate (Qsymia)

Effectiveness of phentermine/topiramate on weight management outcomes in adults: The ICER (Atlas et al., 2022) evidence review included three Phase III studies (EQUIP, EQUATE³⁷, and CONQUER) that evaluated phentermine/topiramate plus lifestyle intervention versus placebo plus lifestyle intervention. In the EQUIP trial, participants in the phentermine 15 mg/topiramate 92 mg group achieved greater weight loss at 1 year than participants in the placebo group (-10.9% versus -1.6%) and higher proportions of participants received weight loss of $\geq 5\%$, $\geq 10\%$, and $\geq 15\%$. Change in mean waist circumference was -10.9 cm for the phentermine/topiramate group and -3.1 cm for the placebo group. Participants in the CONQUER study received one of three treatments — phentermine 15 mg/topiramate 92 mg (high dose), phentermine 7.5 mg/topiramate 46 mg (low dose), or placebo. Participants with

³⁶ The control groups received a placebo (Chanoine et al., 2005; Maahs et al., 2006), conventional treatment alone (Ozkan et al., 2004), or either diet alone, diet and orlistat, or diet orlistat, and exercise (Yu, 2013).

³⁷ One-year outcomes for EQUATE study were not detailed in the ICER report because the trial only lasted 28 weeks.

diabetes in the high-dose and low-dose groups achieved greater weight loss at 1 year (-8.8% and -6.8%, respectively) than participants in the placebo arm (-1.9%).

The systematic review and meta-analysis by Shi et al. (2022) reported that between baseline and 1 year, there was a statistically significant change of -7.97% in percentage bodyweight for phentermine/topiramate plus lifestyle intervention. A greater proportion of phentermine/topiramate participants reduced their bodyweight by $\geq 5\%$ and $\geq 10\%$ compared to the participants who only received lifestyle modification.

Effectiveness of phentermine/topiramate on weight management outcomes in adolescents: Hsia et al. (2020) conducted a randomized, double-blind, placebo-controlled study of phentermine/topiramate in adolescents with obesity (42 participants). Participants were randomized to receive a once-daily placebo, mid-dose of phentermine 7.5 mg/topiramate 46 mg, or top dose of phentermine 15 mg/topiramate 92 mg for 56 days. The mid-dose group lost -4.78% more weight than the placebo group and the top-dose group lost -6.02% more weight than the placebo group; differences were statistically significant. The top-dose group had a -5.2 cm greater reduction in waist circumference than the placebo group. A greater proportion of the top-dose group lost $\geq 5\%$ weight at day 56 compared to the placebo group. Differences in waist circumference and the percentage that lost $\geq 5\%$ weight were not statistically significant.

Setmelanotide (Imcivree)

Effectiveness of setmelanotide on weight management outcomes in adults and adolescents: Setmelanotide is a prescription medicine used in adults and children aged 6 years and older with obesity due to rare genetic conditions that include pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), leptin receptor (LEPR) deficiency, or Bardet-Biedl syndrome (BBS).

One phase 3 RCT (Haqq et al., 2022; 38 patients³⁸) reported that setmelanotide resulted in significant bodyweight reductions in patients with Bardet-Biedl syndrome compared to placebo. After 52 weeks of setmelanotide, 32.33% of patients aged 12 years or older with Bardet-Biedl syndrome reached $\geq 10\%$ reduction in bodyweight. Results were inconclusive in patients with Alström syndrome.

Phentermine (Adipex-P, Lomaira)

Effectiveness of phentermine on weight management outcomes in adults and adolescents: Phentermine monotherapy is approved by the FDA for short-term use (three months) in people 16 years or older with overweight or obesity. Grunvald et al. (2022) conducted a meta-analysis of eight RCTs (ranging from 12 weeks to 28 weeks) that compared phentermine monotherapy with lifestyle interventions (i.e., a low-calorie diet and increased physical activity) versus lifestyle interventions alone. Phentermine doses ranged from 15 to 37.5 mg daily. The phentermine group (205 subjects) lost 4.74 kg and 3.63% more weight than the placebo group (202 subjects) and the difference was statistically significant. The phentermine group was also significantly more likely to achieve $\geq 5\%$ weight loss and $\geq 10\%$ weight loss than the group that received lifestyle interventions alone.

Drug-to-Drug Comparison of FDA-Approved Weight Management Drugs

The STEP 8 RCT (Rubino et al., 2022; 338 subjects with BMI ≥ 30 kg/m² or ≥ 27 kg/m² with at least one weight-related comorbid condition) compared semaglutide 2.4 mg plus lifestyle intervention to liraglutide 3.0 mg plus lifestyle intervention, and both to placebo plus lifestyle intervention. Participants who received semaglutide had a larger mean reduction in weight than participants who received liraglutide (-9.4 percentage points). Participants had significantly greater odds of achieving $\geq 10\%$, $\geq 15\%$, and $\geq 20\%$ weight loss with semaglutide versus liraglutide.

³⁸ Patients aged 6 years or older, included if they had a clinical diagnosis of Bardet-Biedl syndrome or Alström syndrome and obesity (defined as BMI >97th percentile for age and sex for those aged 6 to 15 years and ≥ 30 kg/m² for those aged ≥ 16 years).

ICER reported that when comparing weight management drugs to placebo, semaglutide was superior to all other drugs reviewed (liraglutide, bupropion/naltrexone, and phentermine/topiramate) and had the greatest odds of achieving 5% and 10% weight loss at 1 year (Atlas et al., 2022). Alkhezi et al. (2023) conducted a network meta-analysis of seven RCTs (12,371 subjects) that evaluated the efficacy of weekly tirzepatide 15 mg, weekly tirzepatide 10 mg, weekly semaglutide 2.4 mg, daily semaglutide 0.4 mg, and daily liraglutide 3 mg in adults with overweight or obesity without diabetes. Tirzepatide 10 mg and 15 mg yielded significantly greater weight loss than semaglutide 2.4 mg (-9.23 kg), semaglutide 0.4 mg (-9.73 kg), and liraglutide 3 mg (-16.81 kg). Semaglutide 2.4 mg and 0.4 mg resulted in greater weight loss than liraglutide. Tirzepatide 15 mg also yielded significantly greater percentage weight loss than semaglutide 2.4 mg (-5.13%), semaglutide 0.4 mg (-6.67%), and liraglutide 3 mg (-13.02%). Tirzepatide 10 mg and both semaglutide doses resulted in higher percentages of weight loss than liraglutide. There were higher odds of achieving $\geq 5\%$ to 20% weight loss with tirzepatide 10 mg and 15 mg and semaglutide 2.4 mg than with liraglutide 3 mg.³⁹

FDA-Approved Weight Management Drugs Versus Intensive Behavioral Therapy (IBT)

Liraglutide 3.0 mg (Saxenda)

The SCALE IBT RCT (282 adults with a BMI ≥ 30 kg/m²) and SCALE Insulin RCT (396 adults with a BMI ≥ 27 kg/m², a diagnosis of type 2 diabetes mellitus, and receiving stable treatment with any basal insulin and ≤ 2 oral hypoglycemic medications) evaluated liraglutide 3.0 mg plus IBT versus placebo plus IBT. In both RCTs, participants lost significantly more bodyweight with liraglutide plus IBT versus placebo plus IBT (Atlas et al., 2022).

One RCT (Gudbergson et al., 2021; 168 subjects) randomized patients who underwent a pre-random assignment diet intervention (week -8 to 0) and lost $>5\%$ of their body weight to receive liraglutide 3.0 mg per day or placebo for 52 weeks. From week 0 to 52 there was a significant difference in body weight between the liraglutide and placebo group (mean changes -2.8 kg and 1.2 kg).

Semaglutide 2.4 mg (Wegovy)

The STEP 3 RCT (Wadden et al., 2021; 611 subjects) reported that, in adults with overweight or obesity with at least one weight-related comorbid condition (not diabetes), who were randomly assigned to semaglutide 2.4 mg plus IBT versus placebo plus IBT, the mean percent weight reduction after 68 weeks of treatment was significantly greater in the semaglutide group compared to placebo (-10.3 percentage points). Significantly more participants in the semaglutide 2.4 mg plus IBT had a $\geq 5\%$, $\geq 10\%$, and $\geq 15\%$ reduction in bodyweight compared to the placebo plus IBT groups.

Impact of FDA-Approved Weight Management Drugs on Other Health Outcomes

Outcomes related to quality of life and physical activity

Liraglutide 3.0 mg (Saxenda)

Liraglutide resulted in greater improvement in health status for physical patient-reported outcomes (Atlas et al., 2022). A meta-analysis (Jobanputra et al., 2023; 14 studies) compared the effectiveness of liraglutide and other FDA-approved weight management drugs on self-reported functional outcomes using the 36-item Short Form Survey (SF-36⁴⁰; 3 studies), the Impact of Weight on Quality of Life-Lite Questionnaire (IWQOL-Lite⁴¹), and a combination of both the SF-36 and IWQOL-Lite. The authors

³⁹ Weight loss was reported as difference-in-mean differences. Percentage weight loss was reported as mean differences.

⁴⁰ SF-36 is a 36-item quality of life questionnaire used to indicate the health status of particular populations to help with service planning and to measure the impact of clinical and social interventions.

⁴¹ The Impact of Weight on Quality of Life-Lite (IWQOL-Lite)[®] is a validated, 31-item, self-report measure of obesity-specific quality of life in adults

reported that the standardized mean differences in self-reported functional outcomes significantly favored liraglutide (5 studies; 3,131/1,723 subjects) compared to placebo. In the Shi et al. (2022) systematic review and meta-analysis, the mean difference between participants who received liraglutide 3.0 mg plus lifestyle modification and participants who received lifestyle modification alone was statistically significant for the quality-of-life score but not statistically significant for the depression symptom score. One RCT (Gudbergson et al., 2021; 168 subjects) randomly assigned patients with overweight or obesity and knee osteoarthritis who underwent a pre-random assignment diet intervention (week -8 to 0) and lost >5% of their body weight to liraglutide 3.0 mg per day or placebo for 52 weeks. The RCT found no difference in the Knee Injury and Osteoarthritis Outcome Score pain subscale between the two groups.

Semaglutide 2.4 mg (Wegovy)

The ICER report concluded that semaglutide resulted in greater improvement in physical patient-reported outcomes compared to placebo (Atlas et al., 2022). Another meta-analysis (Jobanputra et al., 2023; 14 studies) reported that the effect of body weight on self-reported functional outcomes significantly favored semaglutide over placebo (4 studies; 2,652/1,530 subjects). In the Shi et al. (2022) study, participants who received semaglutide plus lifestyle modification experienced a larger increase in quality of life than participants who received lifestyle modification alone. One RCT (Kosiborod et al., 2023; 529 subjects) of patients with heart failure with preserved ejection fraction and obesity, reported a significant improvement in physical functioning and 6-minute walk distance in patients taking semaglutide compared to placebo at 52 weeks.

Tirzepatide (Zepbound)

The SURMOUNT-1 trial (Jastreboff et al., 2022) reported that there were greater increases in SF-36 physical function scores among participants who received tirzepatide (5 mg, 10 mg, and 15 mg) plus lifestyle counseling sessions than those who received placebo plus lifestyle counseling sessions.

Bupropion/naltrexone (Contrave)

Shi et al.'s (2022) systematic review and meta-analysis found that persons who received bupropion/naltrexone plus lifestyle modification had a higher mean quality of life score than persons who received lifestyle modification alone but that there was no statistically significant difference in depression symptom scores. A meta-analysis (Jobanputra et al., 2023; 14 studies) reported that the standardized mean differences of the effect of body weight on self-reported functional outcomes significantly favored bupropion-naltrexone (3 studies; 1,876/1,239 subjects; mean difference 0.30) compared to placebo.

Orlistat (Xenical, Alli)

In the Shi et al. (2022) study, there were no statistically significant differences between quality of life and depression symptoms scores of participants who received orlistat plus lifestyle modification and participants who received lifestyle modification alone.

Phentermine/topiramate (Qsymia)

The EQUIP and EQUATE trials included in the ICER (Atlas et al., 2022) report observed greater improvement on the Patient Health Questionnaire-9 (PHQ-9)⁴² in participants who received phentermine 15 mg/topiramate 92 mg compared to those who received a placebo. Participants who received either phentermine 15 mg/topiramate 92 mg or phentermine 7.5 mg/topiramate 46 mg was experienced greater improvement in depression scores than participants who received a placebo.

⁴² The PHQ-9 is an instrument used to screen for depression.

In the Hsia et al. (2020) RCT of phentermine/topiramate, researchers reported no statistically significant differences in PHQ-9 scores between participants who received placebo, phentermine 7.5 mg/ topiramate 46 mg, and phentermine 15 mg/topiramate 92 mg.

In the Shi et al. (2022) study, the mean difference between participants who received phentermine/topiramate plus lifestyle modification and participants who received lifestyle modification alone was statistically significant for the quality-of-life score but not for the depression symptom score.

Outcomes Related to Diabetic and Cardiometabolic Factors

Type 2 diabetes risk assessment

Semaglutide 2.4 mg (Wegovy)

The STEP 1 RCT (1,583 subjects) reported that semaglutide significantly reduced the risk of developing type 2 diabetes compared to placebo (semaglutide -61.1%; placebo -12.9%). During the STEP 5 RCT (295 subjects), the reductions in the risk of developing type 2 diabetes were maintained to week 104 (semaglutide -60.0%; placebo 3.5%). During the STEP 4 RCT run-in period (776 subjects), semaglutide continued to reduce the risk scores (20.6% to 11.1% and further to 7.7%) at week 68. In a post hoc analysis of the STEP trials, using Cardiometabolic Disease Staging to calculate 10-year type 2 diabetes risk scores, Wilkinson et al. (2023) reported that semaglutide 2.4 mg plus lifestyle intervention improved cardiometabolic parameters in adults with obesity (or overweight with weight-related comorbidities). One RCT (Lincoff et al., 2023; 17,604 subjects) of adults with a previous cardiovascular event and obesity reported a significant reduction in death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke at a mean follow-up of 39.8 months.

Tirzepatide (Zepbound)

In the SURMOUNT-1 trial (Jastreboff et al., 2022), 95.3% of the tirzepatide participants who had prediabetes at baseline reverted to normal blood sugar at week 72 compared with 61.9% of placebo participants. Tirzepatide was also associated with improvements in fasting insulin and lipid levels. In the SURMOUNT-2 trial (Garvey et al., 2023), compared to placebo plus lifestyle counseling sessions, tirzepatide 10 mg and 15 mg plus lifestyle counseling sessions were associated with significantly better improvements in fasting glucose (estimated treatment differences -37.9 mg/dL and -37.9 mg/dL, respectively) and fasting insulin (estimated treatment differences -15.6% and -25.9%, respectively). There were also greater improvements in fasting triglycerides, HDL-cholesterol, and non-HDL-cholesterol with tirzepatide (10 mg and 15 mg) than with placebo.

Hemoglobin A1c (glycated hemoglobin, glycosylated hemoglobin, HbA1c, or A1c)

Semaglutide 2.4 mg (Wegovy)

In the STEP 1, 3, and 5 trials, participants who received semaglutide experienced a greater percentage decrease in A1c (-0.45%, -0.51%, and -0.5%, respectively) compared to participants who received a placebo (15%, -0.27%, and -0.2%, respectively). Similarly, in the STEP 8 trial, there was an absolute decrease in A1c among participants who received semaglutide (-0.2%) compared to an increase in A1c among participants who received a placebo (0.1%) (Atlas et al., 2022). However, in the STEP 2 trial that included obese or overweight adults with type 2 diabetes, there was no difference in changes in A1c from baseline between the semaglutide and placebo groups.

Tirzepatide (Zepbound)

In the SURMOUNT-2 trial (Garvey et al., 2023), tirzepatide 10 mg and 15 mg plus lifestyle counseling sessions were associated with significantly better improvements in HbA1c at 72 weeks compared to

placebo plus lifestyle counseling sessions (treatment differences -1.55% and -1.57%, respectively). There were also greater proportions of subjects who achieved HbA1c levels of <7.0%, ≤6.5%, and <5.7% with tirzepatide 10 mg and 15 mg than with placebo.

The network meta-analysis conducted by Alkhezi et al. (2023) found that weekly tirzepatide 10 mg and 15 mg, weekly semaglutide 2.4 mg, daily semaglutide 0.4 mg, and daily liraglutide 3 mg resulted in significant reductions in HbA1c compared to placebo. Tirzepatide and semaglutide yielded significant reductions in HbA1c compared with liraglutide, and tirzepatide yielded significant reductions in HbA1c compared with semaglutide.

Orlistat (Xenical, Alli)

O'Connor et al. (2017) found no statistically different changes in glucose, insulin, or lipid levels in their systematic review of orlistat versus placebo in children and adolescents.

In a systematic review and meta-analysis of orlistat usage in children and adolescents with obesity, Nikniaz et al. (2023) reported that compared to the control group, orlistat was associated with a significant reduction in serum insulin level (mean difference -0.89) but no significant effect on lipid profile (total cholesterol, LDL-C, HDL-C, triglyceride) or serum glucose level.

Phentermine/topiramate (Qsymia)

In the Hsia et al. (2020) RCT of two different doses of phentermine/topiramate versus placebo, there was no statistically significant difference in mean change in fasting glucose, fasting insulin, total cholesterol, or triglycerides.

For participants in the EQUIP trial, change in fasting blood glucose was -0.6 mg/dL for the phentermine/topiramate group and 1.9 mg/dL for the placebo group. Change in cholesterol was -8.4 mg/dL for the phentermine/topiramate group and -5.5 mg/dL for the placebo group. For participants in the CONQUER trial, change in fasting blood glucose was -12.6 mg/dL in the high-dose phentermine/topiramate arm, -9 mg/dL in the low-dose arm, and -5.4 mg/dL in the placebo arm. Change in LDL cholesterol was -2.8 mg/dL in the high-dose phentermine/topiramate arm, -3.6 mg/dL in the low-dose arm, and -2.4 mg/dL in the placebo arm (Atlas et al., 2022).

Bupropion/naltrexone (Contrave)

The COR Diabetes trial (1,625 subjects) reported that bupropion/naltrexone compared to placebo resulted in a significantly greater HbA1c reduction (-0.63% versus -0.14%) as well as a significantly greater percent of patients who achieved an HbA1c of <7% (44.1% versus 26.3%).

Phentermine/topiramate (Qsymia)

Participants in the diabetes mellitus subgroups of the CONQUER study (Atlas et al., 2022) had a 0.4% decrease in HbA1C, whereas participants in the placebo arm had a 0.1% decrease.

Blood pressure

Liraglutide 3.0 mg (Saxenda)

Two RCTs (Atlas et al., 2022; Obesity and Pre-Diabetes, and IBT trials) reported that changes in SBP varied across trials. In one study (SCALE Obesity and Pre-Diabetes), liraglutide demonstrating significant improvements in SBP relative to placebo but another study found no significant difference in SBP between participants receiving liraglutide and those receiving a placebo (SCALE IBT). In network meta-analyses of the trials that reported SBP at 1 year, liraglutide was associated with significant mean

reduction in SBP from baseline at 1 year compared to placebo for both participants with only obesity (without diabetes) and participants with obesity and diabetes (absolute difference 3.1 for participants without diabetes and 3.4 for participants with diabetes).

In a separate network meta-analysis that reported SBP at 1 year and included subjects with obesity with diabetes mellitus, ICER (Atlas et al., 2022) reported that liraglutide demonstrated significant reduction in SBP from baseline at 1 year compared to placebo (estimated difference SBP 3.4).

Semaglutide 2.4 mg (Wegovy)

Three RCTs (STEP 1, 3, and 5) reported that semaglutide was associated with significantly greater improvements in SBP from baseline (-6.2 mmHg, -5.6 mmHg, and -6 mmHg, respectively) compared to placebo (-1.1 mmHg, -1.6 mmHg, and -1.0 mmHg, respectively). In the STEP 2 trial that enrolled obese or overweight adults with type 2 diabetes, participants in the semaglutide arm showed statistically significant improvement in SBP (-3.6 mmHg) compared to those in the placebo arm (-0.5 mmHg) at week 68. Network meta-analyses of trials that reported SBP at 1 year found that semaglutide was associated with greater mean improvement in SBP than placebo for both participants who were obese but did not have diabetes (absolute difference -6.3) and participants who were obese and had diabetes (-4.3).

Tirzepatide (Zepbound)

In the SURMOUNT-1 trial (Jastreboff et al., 2022) of tirzepatide (5 mg, 10 mg, and 15 mg) plus lifestyle counseling sessions versus placebo plus lifestyle counseling sessions, tirzepatide was associated with significantly greater improvements in SBP (estimated treatment difference -6.2 mm Hg) and DBP (estimated treatment difference -4.0 mm Hg). In the SURMOUNT-2 trial (Garvey et al., 2023) of tirzepatide (10 mg and 15 mg) plus lifestyle counseling sessions versus placebo plus lifestyle counseling sessions, tirzepatide yielded significantly greater improvements in SBP (-6.3 mm Hg versus -1.2 mm Hg) and DBP (-2.5 mm Hg versus -0.3 mm Hg).

Bupropion/naltrexone (Contrave)

Four RCTs (COR-BMOD trial; COR-I; 982 subjects) reported no significant difference in SBP for participants receiving bupropion/naltrexone versus placebo. A network meta-analysis reported no significant difference between bupropion/naltrexone and placebo in SBP improvements for obese or overweight patients both with and without diabetes (Atlas et al., 2022).

In the Hsia et al. (2020) RCT of different doses of phentermine/topiramate versus placebo, there was no difference in mean change in SBP between placebo and either dose of phentermine/topiramate. Mean change in DBP from baseline to day 56 was only significantly different between the mid-dose and placebo groups (difference in mean change 6.3).

Orlistat (Xenical, Alli)

In a systematic review of orlistat versus placebo in children and adolescents with obesity, O'Connor et al. (2017) found that orlistat was associated with a statistically significant greater reduction in DBP (mean difference -1.81 mm Hg) but not SBP (mean difference -0.22).

Phentermine/topiramate (Qsymia)

For participants in the EQUIP trial and the CONQUER trial, participants who received phentermine/topiramate experienced greater reductions in SBP than participants who received a placebo (Atlas et al., 2022).

*Metabolic syndrome/abdominal fat***Liraglutide 3.0 mg (Saxenda) versus exercise or placebo**

One RCT (Sandsdal et al., 2023) of 166 adults with obesity and without diabetes who started with an 8-week, low-calorie diet (800 kcal/day) and had a mean body weight loss of 12% in body weight, randomized participants to four arms of 1-year treatment with: placebo, moderate-to-vigorous exercise⁴³, liraglutide 3.0 mg per day, or a combination (exercise plus liraglutide). The previous diet-induced weight loss decreased the severity of metabolic syndrome severity z-score (MetS-Z) from 0.57 to 0.06, which was maintained in the placebo and exercise groups after 1 year. MetS-Z was further decreased by liraglutide (-0.37) and the combination treatment (-0.48) compared to placebo. Abdominal fat percentage decreased by 2.6, 2.8, and 6.1 percentage points in the exercise, liraglutide, and combination groups compared to placebo, respectively.

*C-reactive protein (CRP) levels***Liraglutide 3.0 mg (Saxenda) versus exercise or placebo**

One RCT (Sandsdal et al.; 2023) of 166 adults with obesity and without diabetes who started with an 8-week, low-calorie diet (800 kcal/day) and had a mean loss of 12% in body weight randomized participants into four arms of 1-year treatment with: placebo, moderate-to-vigorous exercise, liraglutide 3.0 mg per day, or a combination (exercise plus liraglutide). The authors reported that CRP⁴⁴ decreased only in the combination group compared with placebo.

Semaglutide 2.4 mg (Wegovy)

In an analysis of RCTs, Verma et al., 2022 (STEP 1, 2, and 3; 3,782 subjects), reported that compared to placebo, semaglutide 2.4 mg resulted in a statistically significant reduction in CRP levels, with an average estimated treatment difference of 44%, 48%, 39% at 68-week follow-up.

*Multiple health outcomes in adolescents***Liraglutide 3.0 mg (Saxenda) versus exercise or placebo**

In a RCT of 251 adolescents, Kelly et al. (2020) reported at week 56, there was no difference between the two groups in glycemic and cardiometabolic results, or in health-related quality of life.

Harms*Harms of FDA-approved GLP-1 weight management drugs***Liraglutide 3.0 mg (Saxenda)**

Harms of liraglutide in adults: In a meta-analysis, Konwar et al. (2022; 14 studies; 6,676 subjects) reported that liraglutide 3.0 mg had higher risk of AEs and a similar risk of serious AEs and discontinuation due to adverse events compared to placebo. In the Shi et al. (2022) systematic review and meta-analysis, the odds ratio of discontinuation due to any adverse event was higher for participants who received liraglutide compared to those who received lifestyle modification alone. The most frequent adverse events (AEs) reported in the SCALE trials for liraglutide compared with placebo were

⁴³ Minimum of 150 min/week of moderate-intensity or 75 min/week of vigorous-intensity aerobic physical activity or an equivalent combination of both.

⁴⁴ CRP is an established biomarker of inflammation (a driver of atherosclerotic cardiovascular disease) and is commonly elevated in people with overweight or obesity.

gastrointestinal-related symptoms, including nausea, constipation, and diarrhea (Atlas et al., 2022). ICER (Atlas et al., 2022) found that all SCALE trials reported higher rates of gallbladder-related and pancreatic adverse events among participants who received liraglutide compared to participants who received a placebo.

Harms of liraglutide in adolescents: In an RCT of 251 adolescents, Kelly et al. (2020) reported that at week 56, the liraglutide group had higher withdrawal rates than the placebo group (10.4% compared to 0%), partly because significantly more adolescents in the liraglutide group experienced gastrointestinal events (e.g., nausea, vomiting, and diarrhea) than adolescents in the placebo group (64.8% versus 36.5%). The gastrointestinal events occurred primarily during the initial 4 to 8 weeks of treatment, when the liraglutide dosage was increased to 3.0 mg.

Semaglutide 2.4 mg (Wegovy)

Harms of semaglutide in adults: In the Shi et al. (2022) systematic review and meta-analysis, there was significantly more discontinuation due to any adverse event among participants who received semaglutide plus lifestyle modification compared to those who received lifestyle modification alone.

All STEP trials reported that more participants in the semaglutide group than in the placebo group discontinued treatment due to gastrointestinal events. All STEP trials reported that nausea and diarrhea were the most common AEs with semaglutide; they were typically temporary, mild-to-moderate in severity, and subsided with time (Atlas et al., 2022). Rates of gastrointestinal AEs among participants receiving semaglutide were as follows: 63.5% in the STEP 2 RCT (Davies et al., 2021; 1,210 subjects), 82.8% in the STEP 3 RCT (Wadden et al., 2021), 59% in the STEP 6 RCT (Kadowaki et al., 2022; 401 subjects), 84.1% in the STEP 8 RCT (Rubino et al., 338 subjects).

Rates of gallbladder and cardiovascular disorders varied by trial. In the STEP 1, 3, and 5 trials, gallbladder-related disorders were more frequent in the semaglutide groups than placebo. However, in STEP 2 and 8, rates of gallbladder-related disorders were higher in the placebo arm than in the semaglutide arm. In the STEP 2 and 8 trials, the rates of cardiovascular disorders were higher in the semaglutide arms than the placebo arm. In the STEP 1, 3, and 5 trials, the rates of cardiovascular disorders were higher in the placebo arm.

Psychiatric disorder event rates (such as insomnia, anxiety, and depression) were higher in semaglutide arms versus placebo arms in the STEP 2, 3, and 5 trials. In the STEP 8 trial, there were higher rates of psychiatric disorder events in the liraglutide arm (15%) compared to the semaglutide (5.6%) and placebo arms (10.6%).

One RCT (Kosiborod et al., 2023; 529 subjects) reported that serious adverse events were significantly less common in the semaglutide group than in the placebo group, with the between-group difference primarily reflecting the lower number of cardiac disorder events in the semaglutide group than in the placebo group.

Tirzepatide (Zepbound)

Harms of tirzepatide in adults: The most commonly reported adverse events in the SURMOUNT-1 trial (Jastreboff et al., 2022) were mild to moderate gastrointestinal events, with most occurring during dose escalation. Withdrawal rates due to adverse events were 4.3% with tirzepatide 5 mg, 7.1% with tirzepatide 10 mg, 6.2% with tirzepatide 15 mg, and 2.6% with placebo. There were no differences in rates of serious adverse events between participants receiving tirzepatide and participants receiving a placebo. In the SURMOUNT-2 trial, Garvey et al. (2023) reported that the most common adverse events for tirzepatide 10 mg and 15 mg were gastrointestinal (e.g., nausea, diarrhea, and vomiting) — most of which occurred during dose escalation and resulted in <5% of withdrawals from the study. There were no between group differences in rates of serious adverse events. The network meta-analysis conducted by

Alkhezi et al. (2023) reported that weekly tirzepatide 10 mg and 15 mg, resulted in more gastrointestinal events than placebo.

Harms of FDA-approved non-GLP-1 weight management drugs

Bupropion/naltrexone (Contrave)

Harms of bupropion/naltrexone in adults: In the Shi et al. (2022) study, participants who received bupropion/naltrexone plus lifestyle modification had significantly higher odds of AEs compared to those who received lifestyle modification alone. The most common AE was nausea, which was generally mild to moderate and temporary.

Orlistat (Xenical, Alli)

Harms of orlistat adults: In the Shi et al. (2022) study, participants who received orlistat plus lifestyle modification had higher odds ratio of discontinuation due to any AE compared to those who received lifestyle modification alone.

Harms of orlistat in adolescents: In the O'Connor et al. (2022) systematic review, thrice daily orlistat 120 mg was associated with more gastrointestinal adverse events than a placebo. Abdominal pain or cramps were reported by 16% to 65% of participants who received orlistat and by 11% to 26% of participants who received a placebo. Flatus, or flatulence, with discharge was reported by 20% to 43% of participants who receive orlistat and by 3% to 11% of participants who received a placebo. Discontinuations due to AEs were rare but approximately twice as common in participants who received orlistat.

Phentermine/topiramate (Qsymia)

Harms of phentermine/topiramate in adults: Participants in the EQUIP, EQUATE, and CONQUER trials who received phentermine 15 mg/topiramate 92 mg were more likely to experience AEs compared to the placebo arms (84.5% versus 72.9%, 83.3% versus 79.8%, and 3.7% versus 3.2%, respectively). Paresthesia, constipation, and dry mouth were among the most common AEs reported in the high-dose groups in all three trials (Atlas et al., 2022). In the Shi et al. (2022) study, the odds of discontinuation due to any AE was greater for participants who received phentermine/topiramate compared to those who received lifestyle modification alone.

Harms of phentermine/topiramate in adolescents: In the Hsia et al. (2020) RCT of phentermine/topiramate, 50% of the placebo group, 40% of the phentermine 7.5 mg/topiramate 46 mg group, and 76.9% of the phentermine 15 mg/topiramate 92 mg group reported AEs. The most frequently reported AEs were nervous system disorders (e.g., headache, paresthesia) and gastrointestinal disorders. Two participants in the phentermine 15 mg/topiramate 92 mg group withdrew from the study due to AEs.

Phentermine (Adipex-P, Lomaira)

Harms of phentermine in adults and adolescents: In the Grunvald et al. (2022) meta-analysis, more people in the phentermine group discontinued treatment due to AEs compared to the placebo group (20% versus 10%). The most common reasons for discontinuation included insomnia, irritability, anxiety, headache, nausea, and increased BP and heart rate.

Summary of findings regarding FDA-approved weight management drugs for adults: There is *clear and convincing evidence* that both FDA approved GLP-1 and non-GLP-1 drugs (liraglutide, semaglutide, tirzepatide, bupropion/naltrexone, and phentermine/topiramate) for weight loss are effective when used as adjuncts to usual care (which includes standard diet and activity and lifestyle recommendations). Use

of these drugs increase the amount of weight lost and percent of body weight lost, and reduces BMI compared to placebo or usual care alone. The recent ICER review concluded that compared to placebo, the weight management drugs demonstrated 4.6% to 13.7% mean greater weight loss.

Liraglutide, semaglutide, and tirzepatide also improved blood sugar, blood pressure, and physical function compared to usual care.

Comparisons across the drugs as well as direct evidence for three drugs (liraglutide, semaglutide, tirzepatide) suggest that semaglutide and phentermine/topiramate achieve greater weight loss than liraglutide and bupropion-naltrexone and that tirzepatide is more effective than semaglutide and liraglutide.

Figure 1. Effectiveness of FDA-Approved Weight Management Drugs for Adults



Summary of findings regarding FDA-approved weight management drugs for children and adolescents: There is *limited evidence* that weight management drugs improve weight loss in adolescents. Two RCTs reported that adolescents who received **semaglutide** had a greater reduction in mean body weight and BMI than adolescents who received a placebo. One RCT evaluating **phentermine/topiramate** in adolescents with obesity reported significant weight loss compared to placebo. Two systematic reviews reported mixed results on the effects of **orlistat** on bodyweight and BMI. For **liraglutide**, one meta-analysis reported that there was no statistically significant difference in weight loss or reduction in BMI, compared to placebo. Bupropion/naltrexone and tirzepatide are not approved for use in adolescents.

Figure 2. Effectiveness of FDA-Approved Weight Management Drugs for Children and Adolescents



Bariatric Surgery

Effectiveness of bariatric surgery compared to nonsurgical interventions on weight management outcomes among adults

Three systematic reviews and meta-analyses have compared the effectiveness of bariatric surgery and nonsurgical interventions, which included no treatment, usual care, exercise behavioral therapy, exercise intervention very-low-calorie diet, and medication (Colquitt et al., 2014 [22 studies; 1,798 participants]; Park et al., 2019 [45 RCTs]; Wang et al., 2021 [19 RCTs, 1,353 subjects]). These studies concluded that bariatric surgery resulted in greater improvement in weight management outcomes (i.e., greater loss of body weight, lower mean BMI, smaller waist circumference) compared with nonsurgical interventions.

Effectiveness of bariatric surgery compared to nonsurgical interventions on other health outcomes among adults

Outcomes related to cardiovascular factors

Wang et al. (2021; 19 studies, 1,353 subjects) reported that among people who received bariatric surgery, systolic and diastolic blood pressure decreased significantly, and triglycerides and high-density lipoprotein cholesterol improved significantly compared to people who received standard care. There were no statistically significant differences between the two groups with regard to total cholesterol and low-density lipoprotein cholesterol.

Outcomes related to diabetic factors

Three meta-analyses have examined the impact of bariatric surgery on outcomes associated with diabetes. In a systematic review and meta-analysis, Park et al. (2019; 24 studies) reported that diabetes remission rates⁴⁵ were significantly higher for people who received all types of bariatric surgery compared to people who received standard care at 1 to 2 years and at 3 to 5 years after surgery. In a meta-analysis, Wu et al. (2023; 24,687 patients) reported that people who received bariatric surgery were significantly more likely to achieve lower HbA1c (<7.0%) within 1 year than people who received a placebo (defined as any therapies other than bariatric surgery, novel glucose-lowering agents, and insulin). Wang et al. (2021; 19 studies, 1,353 subjects) reported that compared to people who received standard care, people who received bariatric surgery were significantly less likely to have metabolic syndrome, and less likely to use insulin, diabetes medications other than metformin, or lipid-lowering drugs at follow-up.

Effectiveness of bariatric surgery on weight management among children and adolescents

Two small studies have examined the effects of bariatric surgery on weight management among children and adolescents. Torbahn et al.'s systematic review (2022) identified one RCT (50 subjects) that compared laparoscopic adjustable gastric banding (LAGB) to a control group that received a behavioral intervention. At 2 years, the authors reported a significant decrease in weight and BMI for LAGB compared to controls (-34.6 kg weight, -12.7 BMI for the LAGB versus - 3.0 kg weight, -1.3 BMI for the control intervention). Järholm et al. (2023; 47 subjects) reported findings from an RCT that concluded that adolescents who received bariatric surgery experienced a significantly greater reduction in BMI compared to the adolescents who received intensive nonsurgical treatment (-12.4 kg/m²) at 2 years follow-up.

Harms of bariatric surgery in adults

Three systematic reviews and meta-analyses have assessed harms associated with bariatric surgery (Colquitt et al., 2014 [22 studies; 1,798 participants]; Park et al. 2019 [45 RCTs]; Wang et al., 2021 [19 RCTs, 1,353 subjects]). Two of these systematic reviews assessed mortality. Colquitt et al. (2014) found that no deaths occurred among studies that reported on mortality, whereas Wang et al. (2021) reported that four deaths occurred, three in control groups due to heart disease and one who received bariatric surgery, whose cause of death was not identified. Colquitt et al. (2014) found that four of the studies included in their systematic review reported on serious adverse events (SAEs) and that rates of SAEs ranged from 0% to 37% in the surgery groups versus 0% to 25% in the no surgery groups. SAEs among persons who received bariatric surgery included site infection, cholecystitis with pancreatitis, pouch dilation (requiring repositioning), pneumonia, severe headaches and strangulated umbilical hernia, and bowel obstruction. Wang et al. (2021) reported that during the follow up period in the studies, 0.28/per person per year adverse events (AEs) were reported in the surgery group, and 0.23/per person per year AEs were reported in the control group. Park et al., 2019 (1,183 Roux-en-Y gastric bypass patients) found that in studies that reported the detailed number of surgical AEs, hernias were the most common adverse event (5.1%), followed by obstruction/stricture (4.0%), gastrointestinal bleeding (2.0%), and ulcers (1.5%).

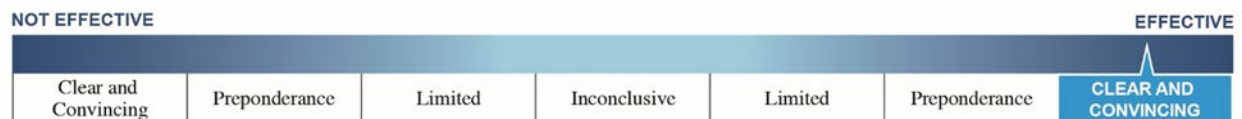
⁴⁵ Diabetes mellitus remission was defined as normalization of serum glucose parameters without glycemetic therapy.

Harms of bariatric surgery in children and adolescents

Järholm et al., 2023 (47 subjects), reported adverse events (n=4) after bariatric surgery were mild but included one cholecystectomy (gallbladder removal). This study reported that surgical patients had a reduction in bone mineral density, while controls were unchanged after 2 years. There were no significant differences between the groups in vitamin and mineral levels, gastrointestinal symptoms (except less reflux in the surgical group), or in mental health at the 2-year follow-up.

Summary of findings regarding bariatric surgery for adults on weight management outcomes: There is *clear and convincing evidence* that bariatric surgery for weight management is effective, with studies reporting that patients lose significantly more weight after surgery compared to patients who receive nonsurgical interventions. Additionally, there is evidence that bariatric surgery improves diabetes and cardiovascular outcomes.

Figure 3. Effectiveness of Bariatric Surgery for Adults



Summary of findings regarding bariatric surgery for adolescents on weight management outcomes: There is *limited evidence* from two RCTs that bariatric surgery for weight management is effective, with studies reporting that patients lose significantly more weight and have significantly lower BMIs after surgery compared to patients who receive nonsurgical interventions.

Figure 4. Effectiveness of Bariatric Surgery for Adolescents



Intensive Behavioral Therapy

Effectiveness of intensive behavioral therapy on weight loss outcomes in adults

A systematic review commissioned by the U.S. Preventive Services Task Force (USPSTF) (LeBlanc et al., 2018) assessed the benefits and harms of IBTs for weight loss in adults with above normal BMI (e.g., ≥25).⁴⁶ Pooled results from 67 RCTs of IBT for weight management in adults (22,065 subjects) indicated that receiving IBT for weight loss was associated with a statistically significant loss of 2.39 more kilograms compared to the control groups⁴⁷ at 12 to 18 months. The systematic review also found that persons who received IBT were significantly more likely to lose 5% of their baseline weight compared to the control groups and that weight loss continued to be significantly greater among those who received IBT in

⁴⁶ The U.S. Preventive Services Task Force uses the terminology “behavior-based weight loss interventions.”

⁴⁷ Control groups received no intervention, (e.g., wait list, usual care, assessment only), minimal intervention (e.g., usual care limited to quarterly counseling sessions), or were attention controls (e.g., received a similar format and intensity of IBT as the intervention group but the content was different).

interventions that lasted up to 36 months. People in the intervention groups also regained less weight than people in the control groups.

Effectiveness of intensive behavioral therapy on weight loss outcomes in children and adolescents

The American Academy of Pediatrics' clinical practice guideline regarding IBT for weight loss among children and adolescents with obesity references a systematic review of 42 trials (6,956 subjects) conducted by O'Connor et al. (2017). The authors found a dose-response pattern where increased contact hours were associated with larger effects. After 6 to 12 months, differences in BMI change were typically statistically significant for interventions that involved 26 or more contact hours and typically not statistically significant for interventions with fewer contact hours. Participants in the intervention groups experienced reductions in BMI while participants in the control groups⁴⁸ experienced no changes in BMI or increases in BMI. The authors also assessed the impact of IBT on change in weight and found that participants who received IBT that involved 26 or more contact hours lost more weight than participants in control groups.

Outcomes related to diabetic factors in adults and children/adolescents

In a pooled analysis of nine trials (3,140 subjects), LeBlanc et al. (2018) determined that there was a significant reduction in the risk of developing type 2 diabetes over 1 to 9 years among adults who received IBT for weight loss compared with participants in comparison groups.

Among the studies of interventions that involved 52 or more contact hours, O'Connor et al. (2017) identified some improvements insulin and glucose measures but no changes in fasting plasma glucose or lipids for children and adolescents.

Outcomes related to cardiovascular factors in children/adolescents

In a pooled analysis of six studies, O'Connor et al. (2017) found that participants who received 52 or more contact hours of IBT had significantly greater improvements in systolic and diastolic blood pressure than participants in control groups.

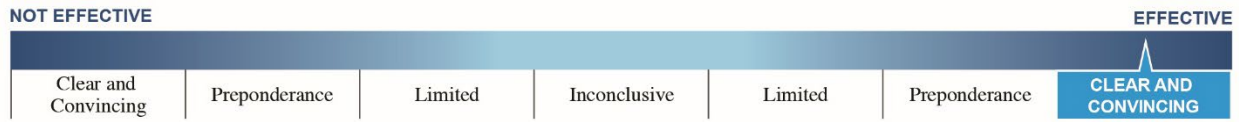
Harms

LeBlanc et al. (2018) concluded that there were no serious harms associated with IBT for weight loss in adults. O'Connor et al. (2017) found no evidence of IBT for weight loss causing harm in children and adolescents.

Summary of findings regarding intensive behavioral therapy for adults: There is *clear and convincing evidence* that IBT for weight loss is effective in reducing weight and BMI in adults based on one systematic review. Participants who received IBT were significantly more likely to lose weight and achieve a $\geq 5\%$ weight loss, as well as have a reduced risk of developing type 2 diabetes, than participants who received a controlled intervention.

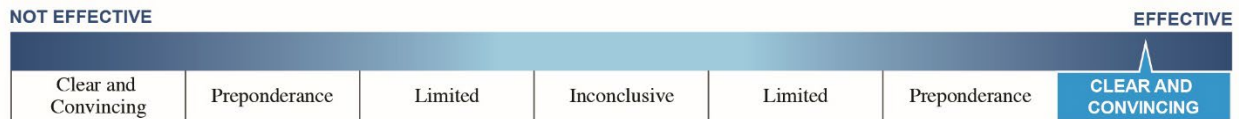
⁴⁸ Control groups received usual care, no intervention, minimal intervention, were assigned to a waitlist, or were attention controls (e.g., received a similar format and intensity of IBT as the intervention group but the content was different).

Figure 5. Effectiveness of Intensive Behavioral Therapy for Adults



Summary of findings regarding intensive behavioral therapy for children and adolescents: There is *clear and convincing evidence* that IBT for weight loss that involves 26 or more contact hours is effective in reducing weight and BMI in children and adolescents based on one systematic review. Participants who received IBT had greater reductions in blood pressure than participants who received comparison interventions.

Figure 6. Effectiveness of Intensive Behavioral Therapy for Children and Adolescents



Summary of Findings

The evidence for the medical effectiveness of FDA-approved weight management drugs, bariatric surgery, and IBT for weight loss is summarized below in Table 6.

Table 6. Summary of Evidence of Medical Effectiveness of Treatments for Weight Loss

Type of Weight Loss Intervention	Impact of Intervention on Weight Loss	Impact of Intervention on Other Health Outcomes	Comparison of Interventions
<p>FDA-approved weight management drugs for adults</p>	<p><i>Clear and convincing evidence</i> that use of both FDA approved GLP-1 and non-GLP-1 weight management drugs (liraglutide, semaglutide, tirzepatide, bupropion/naltrexone, and phentermine/topiramate) combined with usual care (including diet and activity and lifestyle recommendations) results in greater weight loss than usual care alone.</p>	<p><i>Clear and convincing evidence</i> of improvement in health-related quality of life, physical functioning, physical activity, and cardiometabolic health, and reduction in blood pressure and HbA1c.</p>	<p>Comparisons across the drugs suggest that</p> <ul style="list-style-type: none"> • Semaglutide and phentermine/topiramate achieve greater weight loss than liraglutide and bupropion-naltrexone. • Tirzepatide achieves greater weight loss than semaglutide and liraglutide.
<p>FDA-approved weight management drugs for children and adolescents</p>	<p><i>Limited evidence</i> that some FDA approved GLP-1 and non-GLP-1 weight management drugs improve weight loss in adolescents.</p> <ul style="list-style-type: none"> • <i>Limited evidence</i> suggests that semaglutide and phentermine/topiramate improve weight loss and that liraglutide is not associated with improvement in weight loss. • Evidence regarding the impact of orlistat is inconclusive. <p>Bupropion/naltrexone and tirzepatide are not approved for use in children and adolescents.</p>	<p><i>Limited evidence</i> regarding the impact of weight management drugs on the health outcomes in adolescents.</p>	<p>CHBRP did not identify any studies that directly compared the effectiveness of weight management drugs among children and adolescents.</p>
<p>Bariatric Surgery for adults</p>	<p><i>Clear and convincing evidence</i> that bariatric surgery is effective, with studies reporting that patients lose significantly more weight after surgery compared to patients who received nonsurgical interventions.</p>	<p><i>Clear and convincing evidence</i> of improvement in diabetes remission rates, triglycerides and high-density lipoprotein cholesterol, and reduction in HbA1c, systolic and diastolic blood pressure decreased at 1-2 years and at 3-5 years after surgery.</p>	<p><i>Preponderance of evidence</i> favors bariatric surgery compared to nonsurgical interventions.</p>

Bariatric Surgery for children and adolescents	<i>Limited evidence</i> that bariatric surgery is effective for adolescents with obesity, with studies reporting that adolescents lose significantly more weight and have reduced BMIs after surgery compared to similar adolescents who do not have surgery.	CHBRP did not identify any studies that reported on other health outcomes in adolescents.	<i>Limited evidence</i> favors bariatric surgery compared to nonsurgical interventions.
Intensive Behavioral Therapy for adults	<i>Clear and convincing evidence</i> that IBT for adults is associated with significantly greater weight loss and likelihood of achieving a $\geq 5\%$ weight loss.	<i>Clear and convincing evidence</i> that IBT is associated with reduced risk of developing type 2 diabetes.	<i>Clear and convincing evidence</i> that IBT for weight loss is more effective than usual care, no intervention, minimal intervention, and being waitlisted for an intervention.
Intensive Behavioral Therapy for children and adolescents	<i>Clear and convincing evidence</i> that IBT for weight loss is effective in reducing weight and BMI for children and adolescents. IBT interventions with 26 or more hours of contact are more likely to yield greater weight loss in children and adolescents compared to IBT interventions with fewer contact hours.	<i>Clear and convincing evidence</i> that IBT is greater improvements in diabetes and blood pressure control.	<i>Clear and convincing evidence</i> that IBT for weight loss is more effective than usual care, no intervention, minimal intervention, and being waitlisted for an intervention.

Source: California Health Benefits Review Program, 2023.

Key: BMI = body mass index; CHBRP = California Health Benefits Review Program; FDA = U.S. Food and Drug Administration; GLP = glucagon-like peptide-1 (GLP-1); IBT = intensive behavioral therapy.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, SB 839 would require health plans and health policies regulated by DMHC or CDI to provide comprehensive coverage for the treatment of obesity, including coverage for FDA-approved weight management drugs, bariatric surgery, and intensive behavioral therapy (IBT). SB 839 would also require that cost sharing for obesity treatments not be different or separate from treatments for other illnesses, conditions, or disorders.

In addition to commercial enrollees, more than 73% of enrollees associated with CalPERS and more than 80% of Medi-Cal beneficiaries are enrolled in DMHC-regulated plans.⁴⁹ As noted in the *Policy Context* section, SB 839 would not impact Medi-Cal beneficiaries' benefit coverage.

This section reports the potential incremental impacts of SB 839 on estimated baseline benefit coverage, utilization, and overall cost.

Analytic Approach and Key Assumptions

Glucagon-Like Peptide-1 (GLP-1) Drugs for Weight Management

CHBRP identified Saxenda and Wegovy as the GLP-1⁵⁰ drugs for weight management that would be covered under SB 839.

CHBRP's typical claims-based data source does not contain information related to whether these drugs are on a health plan's formulary. Therefore, the data used for this analysis is 2023 pharmacy claims data from Milliman's MyRxConsultant for a national self-insured employer that offers coverage for these drugs and has offered such coverage for several years. CHBRP used this data source as an estimate for unit cost and to set assumptions on baseline utilization.

- Estimated unit cost is based on a 30-day supply, as extended days' supply is not typically dispensed for these drugs.
- Estimated unit cost reflects pricing concessions from manufacturer rebates, which are typically 40%.
- CHBRP estimated that 3.2% of enrollees with obesity would use these drugs if fully covered by their health plan, based on results from the carrier survey on coverage and claims experience data.
- Estimated utilization is consistent with current observed trends for these drugs and an assumption that existing supply chain issues will be fully resolved at baseline due to changes and increasing capacity in manufacturing, and another prescription drug coming to market in 2024.

Other Drugs for Weight Management (Non-GLP-1s)

CHBRP identified Adipex-P, Alli, Contrave, Imcivree, Lomaira, Qsymia, Suprenza, and Xenical as other drugs for weight management that would be covered under SB 839.

- Unit cost was estimated from Milliman's Consolidated Health Research Databases during the first quarter of 2023 and reduced to reflect pricing concessions from manufacturer rebates. CHBRP assumed that manufacturer rebates would be 40% of the cost of these drugs.
- CHBRP estimated that 1.5% of enrollees with obesity and full coverage by their health plan would use these drugs. This is based upon comparing the observed relationship in utilization between

⁴⁹ For more detail, see CHBRP's resource, *Sources of Health Insurance in California*, available at http://chbrp.org/other_publications/index.php.

⁵⁰ One drug, Zepbound, is a dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1

GLP-1 drugs and other drugs for weight management for commercially insured enrollees in California during the first quarter of 2023 in Milliman's Consolidated Health Research Databases.

Bariatric Surgery

Unit cost and utilization is based upon commercially insured enrollees in California during 2022 from Milliman's Consolidated Health Research Databases.

CHBRP identified bariatric surgeries based upon a specific set of CPT codes (see Appendix C). CHBRP includes all professional services (anesthesia, surgical, etc.) and all facility services to estimate the cost of bariatric surgery.

All bariatric surgeries were included in our analysis regardless of the patient's diagnoses. CHBRP is not currently aware of coverage for bariatric surgeries varying by whether the primary diagnosis is severely obese or diabetic.

Intensive Behavior Therapy

Utilization is based upon commercially insured enrollees in California during 2022 from Milliman's Consolidated Health Research Databases, with an assumption that 50% of IBT is reimbursed outside claims systems. To identify the number of enrollees within the database that utilized IBT services, CHBRP took the following approach:

- CHBRP assumed that the following ICD10 diagnosis codes indicate obesity for the purposes of identifying relevant IBT: E66.0, E66.01, E66.09, E66.1, E66.2, E66.8, and E66.9.
- CHBRP assumed that services for the following CPT codes are specific to weight loss and obesity if the enrollee had a diagnosis for obesity during the year: 97802, 97803, 97804, G0270, G0271, G0446, G0447, and G0473.
- CHBRP assumed that services for the following CPT codes are specific to weight loss and obesity if the same medical claim indicated a diagnosis for obesity: 99078, 99080, 99401, and 99402.
- Finally, the number of enrollees was increased by a factor of two to account for the assumption that 50% of IBT is reimbursed outside claims systems.

Enrollees with coverage and without cost-sharing parity were estimated to utilize 5% fewer services, as these enrollees would experience higher cost sharing, which would limit utilization to some degree. CHBRP applied this assumption consistently across GLP-1s, other drugs, IBT, and bariatric surgery.

Enrollees without coverage are assumed to not use any services at baseline. CHBRP assumed that self-pay utilization for the enrollees for whom use is FDA-indicated for weight management is 0% for all treatments.

- Relating to GLP-1s, CHBRP recognizes that in practice there are varying degrees of self-pay, although the drug may not be used consistently with clinical guidelines. The relatively high cost of these services limit utilization for enrollees without coverage. These drugs are intended to be prescribed indefinitely; therefore, temporary use by self-pay individuals would not be consistent with clinical guidelines and the utilization management techniques employed by health plans. Although off-label use of certain prescription drugs has been identified for weight loss, CHBRP assumes that the cost and difficulty obtaining the FDA-indicated drugs for weight management limits their current self-pay use.
- In practice, some enrollees pay directly for the IBT program of their choice. However, relating to IBT, nearly all carriers cover some form of these services.
- Relating to bariatric surgery, the relatively high cost of these services limit utilization for enrollees without coverage.

Assumptions for Baseline Cost Sharing

- For covered services with cost-sharing parity, CHBRP assumed that cost sharing would be similar to average cost sharing (or average coinsurance) for a typical plan design within each metal level or deductible level.
- For covered services without cost-sharing parity, CHBRP assumed that cost sharing would be higher than average cost sharing (or average coinsurance) for a typical plan design within each metal level or deductible level. CHBRP estimated this excess cost sharing to be 50% of the average cost sharing. For instance, CHBRP has assumed that for plans without cost-sharing parity, a plan with 10% average coinsurance would have 15% coinsurance for services without cost-sharing parity.
- CHBRP assumed that cost sharing for IBT was \$0 if indicated in the carrier survey at baseline.

Assumptions for Postmandate Utilization

CHBRP conducted a survey of health plans and health insurers regulated by DMHC or CDI to determine the percentage of enrollees with fully compliant coverage, and coverage with cost sharing parity at baseline. The survey was specific to each treatment.

It is possible that some enrollees incurred expenses related to prescription drugs, treatments, and services for which coverage was denied, but CHBRP cannot estimate the frequency with which such situations occur and so cannot offer a calculation of impact.

Assumptions for Postmandate Benefit Coverage and Cost Sharing

Postmandate, CHBRP assumed that all services are fully covered (for prescription drugs, on-formulary coverage of at least one GLP-1 and one non-GLP-1). CHBRP assumed that cost sharing would be similar to average cost sharing (or average coinsurance) for a typical plan design within each metal level or deductible level.

Assumptions for Postmandate Unit Cost

Unit cost is assumed to be consistent with baseline and the unit cost would not change due to new coverage resulting from SB 839. Unit cost information for IBT is based upon publicly available information from the CDC, estimating that the cost per enrollee per year of a Diabetes Prevention Program (DPP) is \$500.⁵¹ Note that DPP is the “gold standard” of IBT according to CHBRP’s content expert⁵² and includes recommendations such as using a scale.

For further details on the underlying data sources and methods used in this analysis, please see Appendix C.

Baseline and Postmandate Benefit Coverage

At baseline, 10.1% of enrollees with health insurance that would be subject to SB 839 already have fully compliant coverage for *FDA-approved weight management drugs with parity in cost sharing*. Another 3.1% have coverage for the drugs without parity in cost sharing, while the remaining 86.8% of enrollees with health insurance that would be subject to SB 839 have no coverage for GLP-1 weight management drugs. Postmandate, all enrollees with health insurance that would be subject to SB 839 would have fully compliant coverage for GLP-1 weight management drugs with parity in cost sharing. These newly covered enrollees represent 90% of enrollees (an 887% increase from baseline).

⁵¹ [Cost & Value - National DPP Coverage Toolkit](https://coveragetoolkit.org/cost-value-elements/), accessed 10/20/2023 at <https://coveragetoolkit.org/cost-value-elements/>.

⁵² Personal communication, D. Thiara, December 2023.

At baseline, 32.5% of enrollees with health insurance that would be subject to SB 839 already have fully compliant coverage for *FDA-approved non-GLP-1 weight management drugs with parity in cost sharing*. Another 3.5% have coverage for the medication without parity in cost sharing, while the remaining 64% of enrollees with health insurance that would be subject to SB 839 have no coverage for FDA-approved non-GLP-1 weight management drugs. Postmandate, all enrollees with health insurance that would be subject to SB 839 would have fully compliant coverage for FDA-approved non-GLP-1 weight management drugs with parity in cost sharing. These newly covered enrollees represent 68% of enrollees (a 208% increase from baseline).

At baseline, 99.9% of enrollees with health insurance that would be subject to SB 839 have fully compliant coverage for *IBT and bariatric surgery with parity in cost sharing*. Therefore, the 0.1 percentage point increase in coverage would lead to small increases in utilization of both services due to new coverage for a subset of enrollees.

Baseline and Postmandate Utilization

Almost all (95.6%) commercial/CalPERS enrollees in plans and policies regulated by DMHC or CDI have a pharmacy benefit regulated by DMHC or CDI that covers both generic and brand-name outpatient prescription medications.⁵³ Among commercial/CalPERS enrollees, 1.2% do not have a pharmacy benefit and 3.2% have a pharmacy benefit that is not regulated by DMHC or CDI. Because SB 839 does not require creation of a pharmacy benefit — only compliant benefit coverage when a pharmacy benefit is present — baseline benefit coverage for enrollees without a pharmacy benefit or whose pharmacy benefit is not regulated by DMHC or CDI is compliant. In other words, CHBRP assumes SB 839 would have no impact for plans without a regulated pharmacy benefit except for CalPERS, which is discussed in Appendix C.

There are 2,972,677 enrollees with obesity in plans subject to SB 839. At baseline, only 10,008 enrollees use GLP-1 weight management drugs, while 14,838 use non-GLP-1 weight management drugs. Postmandate, due to the 90-percentage point increase in coverage for GPL-1 and 68 percentage point increase in non-GLP-1 weight management drugs, 105,156 enrollees would use GPL-1 and 44,057 enrollees would use non-GLP-1 weight management drugs. The estimates of increased utilization are based on new coverage for both types of weight management drugs due to enactment of SB 839 and the current rates of utilization for enrollees with existing coverage for weight management drugs from Milliman's CHSD and Pharmacy Claims databases (see Appendix C). CHBRP assumes that the same pattern of use of GLP-1 drugs will occur for both obese enrollees and those who are overweight (with comorbidities).

There would be a small change in utilization of IBT (14 additional patients) or bariatric surgery (5 additional surgeries) postmandate due to the existing 99.9% coverage of both benefits at baseline. There is no evidence that IBT or bariatric surgeries would increase due to the increased use of GLP-1 or non-GLP-1 weight management drugs.

Baseline and Postmandate Per-Unit Cost

There is no expected increase in unit costs due to the enactment of SB 839. GLP-1 weight management drugs (\$845) and non-GLP-1 weight management drugs (\$331) would maintain the same average unit cost per year postmandate. However, average cost sharing would increase for GLP-1 weight management drugs by \$27 and decrease for non-GLP-1 weight management drugs by \$12. The increase in cost sharing for GLP-1 drugs is driven by the plans that do not currently cover GLP-1 weight management drugs having higher coinsurance amounts than the plans that already cover GLP-1 weight management drugs. As utilization increases in those plans that had no coverage and higher coinsurance

⁵³ For more detail, see CHBRP's resource *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at http://chbrp.org/other_publications/index.php.

requirements, the average cost sharing would increase. There would also be no change in per-unit costs for bariatric surgery (\$29,522) or IBT (\$500) because of existing coverage for 99.9% enrollees at parity (see Table 1). There is a small estimated reduction (\$1) in cost sharing for IBT.

Baseline and Postmandate Expenditures

Table 8 and Table 9 present baseline and postmandate expenditures by market segment for DMHC-regulated plans and CDI-regulated policies. The tables present per member per month (PMPM) premiums, enrollee expenses for both covered and noncovered benefits, and total expenditures (premiums as well as enrollee expenses).

SB 839 would increase total net annual expenditures by \$1.27 billion or 0.87% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a \$1.12 billion increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a \$150.9 million increase in enrollee expenses for covered and/or noncovered benefits. In Year 2 (see Appendix C) the increase in estimated expenditures would be higher.

Premiums

Changes in premiums as a result of SB 839 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 8, and Table 9), with health insurance that would be subject to SB 839.

The largest increases in premiums are seen in the DMHC-regulated commercial plans, where premiums would increase by 1.0984% in the large-group market, 1.1768% in the small-group market, and 1.1828% in the individual market. Within the individual market commercial plans, enrollees in Covered California plans would see a 1.2086% increase in premiums while their counterparts in grandfathered plans (1.1117%) and nongrandfathered mirror plans (1.0531%) would see slightly lower increases. The CDI-regulated commercial plan enrollees would face much lower premium increases, with a range of 0.4973% in the small-group market and 0.7040% in the individual market.

For enrollees associated with CalPERS in DMHC-regulated plans, there would be a 0.8056% increase in premiums. For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, there would be no impact due to pre-existing Medi-Cal coverage of the services required by SB 839.

Enrollee Expenses

SB 839–related changes in cost sharing for covered benefits (deductibles, copays, etc.) would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 8, and Table 9) with health insurance that would be subject to SB 839 expected to use the relevant tests, treatments, or services during the year after enactment.

CHBRP projects changes to copayments or coinsurance rates due to SB 839's requirement for parity in cost sharing, plus additional coverage of the benefits required by most plans. The total increase in enrollee cost sharing is \$150.9 million, with increases in PMPM by market segments ranging from \$0.4443 for the DMHC-regulated large-group market to \$1.9815 in the DMHC-regulated individual market. CalPERS enrollees would see an increase in cost sharing of \$0.3316 PMPM, which is the smallest increase across all commercial market segments. In the CDI-regulated market, the increases range from \$0.4688 in the large-group market to \$1.4230 in the individual market.

Average enrollee out-of-pocket expenses per user

For enrollees with coverage for GLP-1 weight management drugs, enrollees would experience an average increase in cost sharing of \$27 (from \$91 per unit to \$117 per 30-day prescription dispensed).

This is driven by the tendency for enrollees gaining coverage for GLP-1 weight management drugs to be enrolled in plans with higher cost-sharing requirements, leading to an overall increase in cost sharing per covered service.

For enrollees with coverage for non-GLP-1 weight management drugs at baseline, enrollees would experience an average decrease in cost sharing of \$12 (from \$58 per unit to \$46 per unit). The cost sharing for IBT and bariatric surgery would be unchanged because nearly all plans are already compliant with the requirements of SB 839 for those two treatments. CHBRP estimates are based on claims data and may underestimate the cost savings for enrollees due to carriers' ability to negotiate discounted rates that are unavailable to patients and their families.

Table 7. Impact of SB 839 on Average Annual Enrollee Out-of-Pocket Expenses Per User

	Large Group	Small Group	Individual	CalPERS	Total
Enrollees with Baseline Benefit Coverage and Cost-Sharing Parity	991,500	14,000	-	-	1,005,500
% of Enrollees with Out-of-Pocket Expenses Impact due to SB 839 (a)	12.16%	0.62%	0.00%	0.00%	
Avg Annual Out-of-Pocket Expenses Impact for Enrollees	\$0	\$0	\$0	\$0	\$0
Enrollees with New Cost-Sharing Parity	175,000	1,400	56,000	197,400	429,800
% of Enrollees with Out-of-Pocket Expenses Impact due to SB 839 (a)	2.15%	0.06%	2.04%	22.38%	
Avg Annual Out-of-Pocket Expenses Impact for Enrollees	-\$415	-\$1,454	-\$1,194	-\$389	-\$508
Enrollees with New Benefit Coverage	6,984,500	2,231,600	2,689,000	684,600	12,589,700
% of Enrollees with Out-of-Pocket Expenses Impact due to SB 839 (a)	85.69%	99.31%	97.96%	77.62%	
Avg Annual Out-of-Pocket Expenses Impact for Enrollees	\$779	\$2,114	\$2,517	\$779	\$1,387

Source: California Health Benefits Review Program, 2023.

Notes: Average enrollee expenses includes cost sharing (e.g., deductibles, copays) for covered benefits and out-of-pocket expenses for noncovered benefits.

(a) Not including impacts on premiums.

(b) Benefit coverage for Medi-Cal beneficiaries does not generally include any cost sharing.

Key: CalPERS = California Public Employees' Retirement System.

The presence of a deductible not yet met for the year⁵⁴ could result in the enrollee paying the full unit cost, but hitting the annual out-of-pocket maximum⁵⁵ would result in the enrollee having no further cost sharing.

Postmandate Administrative Expenses and Other Expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies would remain proportional to the increase in premiums. CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs. CHBRP assumes that the administrative cost portion of premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums.

⁵⁴ For estimates of enrollees in plans and policies with deductibles, see CHBRP's resource, *Deductibles in State-Regulated Health Insurance*, available at https://chbrp.org/other_publications/index.php.

⁵⁵ For most enrollees in most plans and policies regulated by DMHC or CDI, applicable copays and coinsurance is limited to \$250, or \$500 for enrollees in the "bronze plans" available from Covered California, the state's ACA marketplace (H&SC 1342.73; IC 10123.1932). Cost sharing could be higher for an enrollee in a plan or policy that includes a deductible.

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

Because the change in average premiums exceeds 1% for several market segments (see Table 1, Table 8, and Table 9), CHBRP would expect a measurable change in the number of uninsured persons due to the enactment of SB 839, especially in markets where the enrollee bears the majority of any added premium costs. For example, despite an estimated 1.18% increase in the DMHC-regulated individual market, about 75% of the enrollees are in Covered California plans where tax credits are linked to the 2nd lowest silver premium available in the region, such that enrollees are partially protected from premium increases for new benefit mandates because they also cause the tax credits to increase commensurately. The premium increases in the CDI-regulated and DMHC-regulated CalPERS market segments are not above 1%, so CHBRP would anticipate that coverage losses are limited to enrollees in DMHC-regulated plans, with a specific focus on individual market plans offered outside of Covered California where tax credits to subsidize the cost are unavailable.

Due to an estimated premium increase of greater than 1% due to SB 839 (Table 1), CHBRP estimates that the increases in premiums would cause 10,000 enrollees to lose or drop coverage. In this case, the aggregate premium increases of more than 1% in all four markets could lead to an increase in the uninsured of 0.43%, but the majority of newly uninsured would likely come from enrollees in the DMHC-regulated individual market and the DMHC-regulated small-group market where premium increases are more likely to be passed on as enrollee out-of-pocket premium costs rather than absorbed by federally funded tax credits or employer contributions to health insurance coverage.

Changes in Public Program Enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of SB 839.

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

For commercial insurance enrollees in DMHC-regulated and CDI-regulated health plans, there are no public programs or other payers that would cover the newly covered prescription drugs at baseline. It is likely that public programs do provide IBT services (using the DPP model), but it appears that 100% of the regulated market already has coverage at baseline for IBT. CHBRP does not anticipate a cost shift from other payers or public programs due to the additional benefits provided to commercial enrollees required by SB 839.

Table 8. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2024

	DMHC-Regulated						CDI-Regulated			TOTAL
	Commercial Plans (by Market) (a)			Publicly Funded Plans Medi-Cal (excludes COHS) (c)			Commercial Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS (b)	Under 65	65+	Large Group	Small Group	Individual	
Enrollee Counts										
Total enrollees in plans/policies subject to state mandates (d)	7,780,000	2,212,000	2,618,000	882,000	8,043,000	774,000	371,000	35,000	127,000	22,842,000
Total enrollees in plans/policies subject to SB 839	7,780,000	2,212,000	2,618,000	882,000	0	0	371,000	35,000	127,000	14,025,000
Premium Costs										
Average portion of premium paid by employer (e)	\$473.17	\$417.10	\$0.00	\$581.85	\$254.61	\$543.16	\$490.57	\$517.32	\$0.00	\$93,424,638,000
Average portion of premium paid by enrollee	\$122.17	\$180.13	\$645.33	\$113.49	\$0.00	\$0.00	\$180.61	\$168.99	\$626.90	\$39,493,007,000
Total Premium	\$595.34	\$597.23	\$645.33	\$695.34	\$254.61	\$543.16	\$671.18	\$686.31	\$626.90	\$132,917,645,000
Enrollee Expenses										
Cost-sharing for covered benefits (deductibles, copays, etc.)	\$40.98	\$127.06	\$168.73	\$49.17	\$0.00	\$0.00	\$99.22	\$184.48	\$208.51	\$13,857,141,000
Expenses for noncovered benefits (f)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0
Total Expenditures	\$636.33	\$724.29	\$814.06	\$744.50	\$254.61	\$543.16	\$770.40	\$870.80	\$835.40	\$146,774,786,000

Source: California Health Benefits Review Program, 2023.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.7% are state retirees, state employees, or their dependents. About one in five (22.5%) of these enrollees has a pharmacy benefit not subject to DMHC. However, CHBRP has projected an impact for those enrollees (See Appendix C).

(c) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Includes those who are also Medicare beneficiaries.

(d) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.

(e) In some cases, a union or other organization — or Medi-Cal for its beneficiaries.

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

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

Table 9. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2024

	DMHC-Regulated						CDI-Regulated			TOTAL
	Commercial Plans (by Market) (a)			Publicly Funded Plans Medi-Cal (excludes COHS) (c)			Commercial Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS (b)	Under 65	65+	Large Group	Small Group	Individual	
Enrollee Counts										
Total enrollees in plans/policies subject to state mandates (d)	7,780,000	2,212,000	2,618,000	882,000	8,043,000	774,000	371,000	35,000	127,000	22,842,000
Total enrollees in plans/policies subject to SB 839	7,780,000	2,212,000	2,618,000	882,000	0	0	371,000	35,000	127,000	14,025,000
Premium Costs										
Average portion of premium paid by employer (e)	\$5.1972	\$4.9085	\$0.0000	\$4.6872	\$0.0000	\$0.0000	\$2.4398	\$3.2723	\$0.0000	\$677,347,000
Average portion of premium paid by enrollee	\$1.3419	\$2.1198	\$7.6333	\$0.9143	\$0.0000	\$0.0000	\$0.8982	\$1.0689	\$4.4135	\$442,210,000
Total Premium	\$6.5391	\$7.0283	\$7.6333	\$5.6014	\$0.0000	\$0.0000	\$3.3381	\$4.3412	\$4.4135	\$1,119,556,000
Enrollee Expenses										
Cost-sharing for covered benefits (deductibles, copays, etc.)	\$0.4443	\$1.4678	\$1.9815	\$0.3316	\$0.0000	\$0.0000	\$0.4688	\$0.9772	\$1.4230	\$150,867,000
Expenses for noncovered benefits (f)	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
Total Expenditures	\$6.9834	\$8.4961	\$9.6148	\$5.9330	\$0.0000	\$0.0000	\$3.8069	\$5.3184	\$5.8365	\$1,270,424,000
Postmandate Percent Change										

Percent change insured premiums	1.0984%	1.1768%	1.1828%	0.8056%	0.0000%	0.0000%	0.4973%	0.6325%	0.7040%	0.8423%
Percent Change total expenditures	1.0975%	1.1730%	1.1811%	0.7969%	0.0000%	0.0000%	0.4941%	0.6108%	0.6986%	0.8656%

Source: California Health Benefits Review Program, 2023.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.7% are state retirees, state employees, or their dependents. About one in five (22.5%) of these enrollees has a pharmacy benefit not subject to DMHC. However, CHBRP has projected an impact for those enrollees (See Appendix C).

(c) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Includes those who are also Medicare beneficiaries.

(d) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.

(e) In some cases, a union or other organization — or Medi-Cal for its beneficiaries.

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

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

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, SB 839 would require comprehensive coverage for obesity treatments including drugs approved by the FDA with an indication for chronic weight management, bariatric surgery, and intensive behavioral therapy (IBT). SB 839 would also require that cost sharing for obesity treatments not be different or separate from treatments for other illnesses, conditions, or disorders.

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 impact⁵⁶ of SB 839 on change in body weight and additional health-related outcomes, barriers to diagnosis and treatment, potential treatment harms, and potential disparities. See *Long-Term Impacts* for discussion of premature death, economic loss, and social drivers of health.

Estimated Public Health Outcomes

Measurable health outcomes relevant to SB 839 include primary outcomes such as change in body weight, percent excessive weight loss, and mean body mass index (BMI) change. Additional health-related outcomes included diabetes risk, glycated hemoglobin (A1C), systolic blood pressure (SBP), diastolic blood pressure (DBP), waist circumference, functional quality of life, and harms of FDA-approved weight management drugs.

As presented in *Medical Effectiveness*, there is either *clear and convincing evidence* or a *preponderance of evidence* that drugs approved by the FDA with an indication for chronic weight management, bariatric surgery, and IBT are all effective for weight management.

As presented in *Benefit Coverage, Utilization, and Cost Impacts*, at baseline, it is estimated that among enrollees with health insurance that would be subject to SB 839, there is currently fairly high levels of coverage for bariatric surgery and IBT (99.9%) and relatively low levels of SB 839 compliant coverage for FDA-approved glucagon-like peptide-1 (GLP-1)⁵⁷ (10.1%) and non-GLP-1 (32.5%) weight management drugs.

It is estimated that as a result of SB 839, **utilization of obesity treatments would increase** as follows for the approximately 14 million enrollees (36% of all Californians) with health insurance that would be subject to SB 839:

- 95,148 enrollees using FDA-approved GLP-1 weight management drugs;
- 29,219 enrollees using FDA-approved non-GLP-1 weight management drugs;
- 5 enrollees receiving bariatric surgery; and
- 14 enrollees receiving intensive behavioral therapy (IBT) for weight loss.

Based on the literature review presented in *Medical Effectiveness*, it is estimated that across these 124,000 new utilizers of obesity treatments, they would have an average weight loss of between 5% and 14% compared to non-utilizers. The level of weight loss would depend on a number of factors including the specific treatment utilized and specific patient level factors. In addition, there would be, on average, some level of improvement in obesity-related health outcomes such as decreased diabetes risk and improvement in hemoglobin (A1C) levels, improvement in blood pressure, and improved functional quality of life.

In the first year postmandate, 14 million enrollees with health insurance subject to SB 839 would experience a change in benefit coverage and 124,000 would newly utilize obesity treatments. As a result,

⁵⁶ CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

⁵⁷ One drug, Zepbound, is a dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1

these enrollees would experience a 5% to 14% reduction in body weight by and related health improvements, which is supported by evidence that obesity treatments are medically effective.

Potential Harms from SB 839

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 839, there is evidence to suggest that an increase in the use of obesity treatments could result in harm. Potential harms associated with the use of FDA-approved drugs for weight management include gastrointestinal-related symptoms, including nausea, vomiting, constipation, and diarrhea; paresthesia (i.e., burning or prickling sensation, often occurring in the hands, arms, legs, or feet); dry mouth; insomnia; irritability; anxiety; headache; and increased blood pressure and heart rate. Adverse events may contribute to discontinuation of the drug, which can impact overall medical effectiveness of the treatment. It is unclear if long-term use is associated with more severe and persistent harms.

Impact on Disparities⁵⁸

As described in the *Background* section, there are many factors that serve as barriers to seeking and accessing obesity treatments. These barriers can serve to create disparities in rates of utilization of obesity treatments and overall rates of obesity. Each of these factors and the impact that SB 839 may have on addressing these barriers and resulting disparities is described below.

- **Stigma:** It is unclear how SB 839 would impact stigma surrounding obesity and obesity treatments.
- **Racism and discrimination:** There is no evidence to suggest that SB 839 would decrease racism and discrimination related to obesity diagnosis and treatment. Therefore, it is unlikely that SB 839 would reduce racial and ethnic disparities in obesity rates or treatment for obesity.
- **Location:** It is possible that people living in rural areas who are more likely to face challenges in accessing obesity treatments may benefit from SB 839 if an increase in coverage for weight management drugs includes medications available via mail that could be sent to individuals living in more remote settings.
- **Lack of awareness:** It is possible that the passage of SB 839, and the resulting media attention to the new law, could create additional awareness of these treatments and insurance coverage for them, which may increase the rates at which individuals seek out treatment.
- **Expense:** The high cost of some obesity treatments make them inaccessible for insured patients with lower incomes (Levi et al., 2023). For individuals with health insurance subject to SB 839, FDA-approved drugs for weight management could become more accessible due to the new insurance coverage requirements. Yet, because the cost sharing for some drugs would be higher than for previously covered treatments, the benefits of the additional coverage from SB 839 may be seen predominantly by those insured with higher incomes.
- **Supply:** As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, it is assumed that by the time SB 839 would be in effect, the supply chain issues with GLP-1 drugs will be resolved. This is something that is assumed to occur over time whether or not SB 839 is passed.

⁵⁸ For details about CHBRP's methodological approach to analyzing disparities, see the *Benefit Mandate Structure and Unequal Racial/Ethnic Health Impacts* document here: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

Benefit Mandate Applicable Populations and Unequal Racial/Ethnic Health Impacts

SB 839 applies to the health insurance of enrollees in CDI-regulated policies and other enrollees in DMHC-regulated plans but would not be applicable to the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans. As Medi-Cal beneficiaries already have coverage for the treatments included under SB 839 (i.e., GLP-1 and non-GLP-1 drugs with FDA indication for weight management, bariatric surgery, and IBT for weight loss), the exclusion of Medi-Cal beneficiaries from SB 839 would not result in disparities in coverage for obesity treatments.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of SB 839, 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 generally 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

Supply chain issues have been a struggle for glucagon-like peptide-1 (GLP-1) weight management drugs. While CHBRP assumes no supply chain issues constraining supply of the drugs covered by SB 839 for this analysis, if they did occur in new or existing GLP-1 drugs, it could limit utilization despite the existence of insurance coverage for the benefit. In Year 2 and future years, new prescription drugs including the recently approved Zepbound to address weight management will be on the market and result in additional use of GLP-1 drugs.⁵⁹ Although CHBRP anticipates offset due to reduced cardiovascular events in Year 2 postmandate, other reductions in utilization might occur in the long term if people are able to continue taking GLP-1 drugs long term and maintain weight loss, which would improve health status.

Cost Impacts

As new GLP-1 weight management drugs come to the market at higher unit costs, SB 839 could result in additional expenditures. However, if SB 839 is interpreted to require coverage of one drug in each class of medication, perhaps generic GLP-1 alternatives could be covered instead of the higher cost brand-name drugs currently on the market or coming to market, resulting in a shift to drugs with lower unit cost. As mentioned above, long-term weight maintenance could also result in reductions in expensive diseases like diabetes, cardiovascular disease, hypertension, and cancer. While those savings would not materialize in the first 2 years postmandate, the long-term savings could offset some of the expense. However, given the price of the drug (\$14,000+ per year), the savings created through improved health status, weight maintenance, and reduction in cost of treating chronic disease with reduction in obesity (e.g., diabetes medications, insulin, etc.) are unlikely to completely offset the expenditures.

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.

As a result of SB 839, CHBRP estimates approximately 95,148 enrollees would use FDA-approved GLP-1 weight management drugs, 29,219 enrollees would use FDA-approved non-GLP-1 weight management drugs, five enrollees would receive bariatric surgery, and fourteen enrollees would receive intensive behavioral therapy (IBT) for weight loss within 1-year postmandate. It is estimated that these individuals would lose between 5% and 14% of their body weight. Therefore, public health impacts would be likely to accrue to these individuals outside of the 1-year time frame as they continue to lose and maintain their weight loss. As reported in the *Medical Effectiveness* section, there was limited evidence to evaluate the long-term benefits of obesity treatments. Therefore, while this limited evidence suggests that

⁵⁹ One drug, Zepbound, is a dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1

we would continue to see a reduction in the overall prevalence of obesity and obesity-related chronic disease, including a reduction in cardiovascular disease, hypertension (i.e., high blood pressure), type 2 diabetes, and certain types of cancer, the magnitude of these benefits is unknown.

Impacts on Premature Death and Economic Loss

Premature death

Premature death, measured by years of potential life lost (YPLL), is often defined as death occurring before the age of 75 years (NCI, 2019).⁶⁰ Fontaine et al. (2003) found that the life expectancy for an adult with a severe level of obesity (i.e., BMI > 45) reduced by a range of 5 to 20 YPLL — depending on sex and race and ethnicity. According to the CDC Wonder online database, 1,071 adult deaths in California were attributed to obesity (and other hyperalimentation), equal to a rate of 3.7 per 100,000 persons, in 2021 (CDC, 2021). Although SB 839 has the potential to impact premature death, the extent to which this may occur is unknown.

Economic loss

Economic loss associated with disease is generally presented in the literature as an estimation of the value of the YPLL in dollar amounts (i.e., valuation of a population's lost years of work over a lifetime). In addition, morbidity associated with the disease or condition of interest can also result in lost productivity by causing a worker to miss days of work due to illness or acting as a caregiver for someone else who is ill. Cawley et al. (2021b) found that obesity increases job absenteeism (either due to injury or illness) by an average of 4.68 days per year per obese individual in California. In addition, they estimated that each additional unit of BMI increased the average days of work lost by 0.20 days per year. This translated into productivity losses ranging from \$1.05 billion to \$2.1 billion in productivity losses per year in California.⁶¹ It is estimated that SB 839 would increase utilization of obesity treatments by 111,100 people per year. Assuming an average weight loss of 10% (i.e., the mid-point of the range of 5%-14%), this would translate into an approximate decrease in lost productivity of 83,000 days per year or \$1.9 to \$3.8 million per year. This savings would grow over time as the cumulative pool of people who have lost weight using obesity treatments grows. Similarly, estimates across the United States have shown that a reduction in the average BMI by 5% could save nearly \$30 billion in 5 years, save more than \$150 billion in 10 years, and more than \$600 billion in 20 years (Wang et al., 2011).

⁶⁰ For more information about CHBRP's public health methodology, see http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

⁶¹ Translated into 2023 dollars using <https://www.usinflationcalculator.com/>

APPENDIX A TEXT OF BILL ANALYZED

On May 15, 2023, the California Senate Committee on Health requested that CHBRP analyze SB 839, as amended on May 10, 2023.

AMENDED IN SENATE MAY 10, 2023

AMENDED IN SENATE MARCH 20, 2023

CALIFORNIA LEGISLATURE— 2023–2024 REGULAR SESSION

SENATE BILLNO. 839

Introduced by Senator Bradford

February 17, 2023

An act to add Section 1374.6 to the Health and Safety Code, and to add Section 10123.62 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 839, as amended, Bradford. Obesity Treatment Parity Act.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act's requirements a crime. Existing law provides for the regulation of disability and health insurers by the Department of Insurance. Existing law sets forth specified coverage requirements for plan contracts and insurance policies, and limits the copayment, coinsurance, deductible, and other cost sharing that may be imposed for specified health care services.

This bill would require an individual or group health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2025, to include comprehensive coverage for the treatment of obesity in the same manner as any other illness, condition, or disorder for purposes of determining deductibles, lifetime dollar limits, copayment and coinsurance factors, and benefit year maximums for deductibles and copayment and coinsurance factors.

Because a willful violation of these provisions by a health care service plan would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

BILL TEXT

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

SECTION 1. This act shall be known, and may be cited, as the Obesity Treatment Parity Act.

SEC. 2. Section 1374.6 is added to the Health and Safety Code, to read:

1374.6. (a) An individual or group health care service plan contract that is issued, amended, or renewed on or after January 1, 2025, shall include comprehensive coverage for the treatment of obesity, including coverage for intensive behavioral therapy, bariatric surgery, and FDA-approved antiobesity medication.

(b) Coverage criteria for FDA-approved antiobesity medications shall not be more restrictive than the FDA-approved indications for those treatments.

(c) Coverage under this section shall not be different or separate from coverage for any other illness, condition, or disorder for purposes of determining deductibles, lifetime dollar limits, copayment and coinsurance factors, and benefit year maximums for deductibles and copayment and coinsurance factors.

(d) This section does not prohibit a plan from applying utilization management to determine the medical necessity for treatment of obesity under this section if appropriateness and medical necessity determinations are made in the same manner as those determinations are made for the treatment of any other illness, condition, or disorder covered by a contract.

(e) For purposes of this section, "FDA-approved antiobesity medication" means any medication approved by the United States Food and Drug Administration with an indication for chronic weight management in patients with obesity.

(f) This section does not apply to a specialized health care service plan contract that covers only dental or vision benefits or a Medicare supplement contract.

SEC. 3. Section 10123.62 is added to the Insurance Code, to read:

10123.62. (a) An individual or group health insurance policy that is issued, amended, or renewed on or after January 1, 2025, shall include comprehensive coverage for treatment of obesity, including coverage for intensive behavioral therapy, bariatric surgery, and FDA-approved antiobesity medication.

(b) Coverage criteria for FDA-approved antiobesity medications shall not be more restrictive than the FDA-approved indications for those treatments.

(c) Coverage under this section shall not be different or separate from coverage for any other illness, condition, or disorder for purposes of determining deductibles, lifetime dollar limits, copayment and coinsurance factors, and benefit year maximums for deductibles and copayment and coinsurance factors.

(d) This section does not prohibit an insurer from applying utilization management to determine the medical necessity for treatment of obesity under this section if appropriateness and medical necessity determinations are made in the same manner as those determinations are made for the treatment of any other illness, condition, or disorder covered by a policy.

(e) For purposes of this section, "FDA-approved antiobesity medication" means any medication approved by the United States Food and Drug Administration with an indication for chronic weight management in patients with obesity.

(f) This section does not apply to a specialized health insurance policy that covers only dental or vision benefits or a Medicare supplement policy.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes

the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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 effectiveness of FDA-approved weight management drugs, bariatric surgery, and IBT for weight loss were identified through searches of PubMed, the Cochrane Library, Web of Science, the Cumulative Index of Nursing and Allied Health Literature (CINAHL), and PsycINFO. Websites maintained by the following organizations were also searched: the Agency for Healthcare Research and Quality (AHRQ), the National Institute for Health and Clinical Excellence (NICE), U.S. Preventive Services Task Force (USPSTF), World Health Organization (WHO), 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.

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 1,655 articles, of which 175 were reviewed for inclusion in this report. A total of 50 studies were included in the medical effectiveness review for SB 839.

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*.⁶² 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*.

⁶² Available at: http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

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

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

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

A grade of *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)

Adipex-P	Obesity
Alli	Obesity, Morbid
Bariatric Surgery	Orlistat
Behavior Therapy	Phentermine
Bupropion	Phentermine-topiramate
Bupropion-naltrexone	Qsymia
Cochrane Review	Practice Guideline
Contrave	Randomized Controlled Trial
Controlled Clinical Trial	Saxenda
Gastric Bypass	Semaglutide
Gastroplasty	Setmelanotide
Imcivree	Suprenza
Jejunioileal Bypass	Systematic Review
Liraglutide	Wegovy
Lomaira	Xenical
Meta Analysis	
Morbid Obesity	

APPENDIX C 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.⁶³ 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.⁶⁴

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

Analysis-Specific Data Sources

Current coverage of obesity treatments for commercial enrollees was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represent 80.5% of commercial enrollees with health insurance that can be subject to state benefit mandates.

For this analysis, CHBRP relied on CPT[®] codes to identify relevant services. CPT copyright 2022 American Medical Association. All rights reserved. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. CPT is a registered trademark of the American Medical Association.

As discussed above, the primary data sources for utilization included the 2022 through Q1 2023 Consolidated Health Cost Guidelines[™] Sources Database (CHSD), 2022 through 2023 pharmacy claims data from Milliman's MyRxConsultant, and information on the utilization of IBT from carrier surveys.

Detailed Cost Notes regarding Analysis-Specific Caveats and Assumptions

The analytic approach and key assumptions are determined by the subject matter and language of the bill being analyzed. As a result, analytic approaches may differ between topically similar analyses, and therefore the approach and findings may not be directly comparable.

Total estimated scripts filled and unit costs for glucagon-like peptide 1 (GLP-1) agonist drugs with FDA indication for weight management are based upon the real-world experience of a large, self-insured plan. Therefore, the estimated total costs of coverage implicitly reflect the physician prescribing patterns, demographics, and medication persistence of this population. Within Table 1, the total number of utilizers of GLP-1s and other drugs reflects the number of individuals anticipated to be utilizing the drugs on any given day during 2024, at baseline and postmandate. The total number of individuals taking the drugs throughout the year would be higher than this figure and vary depending on the number of new medication starts and medication persistence. As is standard for CHBRP analyses, our estimates do not include any "ramp up" to full coverage.

Many enrollees who use IBT services will not complete 12 sessions as recommended by the USPTF. In fact, 30% of these enrollees will not complete a second session and only 10% of enrollees will complete

⁶³ CHBRP's authorizing statute, available at https://chbrp.org/about_chbrp/index.php, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

⁶⁴ See method documents posted at <https://www.chbrp.org/about/analysis-methodology/cost-impact-analysis>; in particular, see *2022 Cost Analyses: Data Sources, Caveats, and Assumptions*.

all 12.⁶⁵ CHBRP's estimates of the unit cost of IBT consider that many enrollees will not complete all 12 visits. Furthermore, many health plans and policies cover and reimburse providers of IBT outside the claims system; therefore, our estimates of enrollees engaging IBT are based upon a combination of our analysis of the Consolidated Health Cost Guidelines™ Sources Database (CHSD) and carrier surveys.

Although CalPERS has a high percentage of individuals without prescription drug benefits regulated by DMHC or CDI, CHBRP has assumed that 100% of individuals will be impacted by this mandate because CalPERS treats its self-funded pharmacy benefit consistently across all plans (HMOs and PPOs).

Determining Public Demand for the Proposed Mandate

CHBRP reviews public demand for benefits by comparing the benefits provided by self-insured health plans or policies (which are not regulated by the DMHC or CDI and therefore not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS have the largest number of enrollees. The CalPERS PPOs currently provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask plans and insurers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

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

In order to develop Table 10, CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of SB 839 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. To generate this table, CHBRP reviewed the literature and consulted content experts about the possibility of varied second-year impacts and applied what was learned to a projection of a second year of implementation.

CHBRP assumed that enrollees who utilize GLP-1s would have a reduced frequency of cardiovascular events in the second year of the mandate, which would result in medical claim cost reductions of \$100 per GLP-1 user per year in 2025. This figure is derived from the ICER report (Atlas et al., 2022). The ICER report modeled a population that is generally consistent with the population using GLP-1s for weight loss postmandate, with an average age between 45 and 50.

Some of ICER's assumptions may justify using a higher or lower offset than the \$100 figure presented in the report. The California commercial population likely has a higher unit cost for cardiovascular events than the population used in the ICER report, which would suggest a higher offset. However, the ICER report assumed full medication persistence, but actual persistence would likely be below 100% and suggest a smaller offset.

Some differences in expenditures and utilization are due to population changes between 2024 and 2025. Other differences are due to increased take-up of GLP-1 and the additional spending associated with it.

⁶⁵ Personal Conversation, Dr. Diana Thiara, UCSF, October 2, 2023.

Table 10. Impacts of SB 839 on Benefit Coverage, Utilization, and Cost, 2025

	Baseline (2025)	Postmandate Year 1 (2025)	Increase/Decrease	Change Postmandate
Benefit Coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	22,942,000	22,942,000	0	0.0%
Total enrollees with health insurance subject to SB 839	14,091,000	14,091,000	0	0.0%
Percent of enrollees with fully compliant coverage and parity in cost sharing for GLP-1 drugs	10.1%	100.0%	90%	885.9%
Percent of enrollees with coverage and without parity in cost sharing for GLP-1 drugs	3.0%	0.0%	-3%	-100.0%
Percent of enrollees without coverage for GLP-1 drugs	86.8%	0.0%	-87%	-100.0%
Percent of enrollees with fully compliant coverage and parity in cost sharing for non-GLP-1 drugs	32.4%	100.0%	68%	208.2%
Percent of enrollees with coverage and without parity in cost sharing for non-GLP-1 drugs	3.5%	0.0%	-3%	-100.0%
Percent of enrollees without coverage for non-GLP-1 drugs	64.1%	0.0%	-64%	-100.0%
Percent of enrollees with fully compliant coverage and parity in cost sharing for bariatric surgery	99.9%	100.0%	0%	0.1%
Percent of enrollees with coverage and without parity in cost sharing for bariatric surgery	0.0%	0.0%	0%	-100.0%
Percent of enrollees without coverage for bariatric surgery	0.1%	0.0%	0%	-100.0%
Percent of enrollees with fully compliant coverage and parity in cost sharing for IBT for weight loss	100.0%	100.0%	0%	0.0%
Percent of enrollees with coverage and without parity in cost sharing for IBT for weight loss	-0.1%	0.0%	0%	-100.0%
Percent of enrollees without coverage for IBT for weight loss	0.1%	0.0%	0%	-100.0%
Utilization and Cost				
Number of enrollees with obesity	2,987,732	2,987,732	-	0.00%
Number of overweight enrollees with comorbidities	516,226	516,226	-	0.00%
Number of enrollees using FDA-approved GLP-1 weight management drugs	17,584	184,956	167,373	951.87%
Average unit cost of FDA-approved GLP-1 weight management drugs	\$845	\$845	\$0	0.00%
Average cost sharing for FDA-approved GLP-1 weight management drugs	\$90	\$117	\$27	29.70%

Number of enrollees using FDA-approved non-GLP-1 weight management medication	18,609	55,350	36,742	197.44%
Average unit cost of FDA-approved non-GLP-1 weight management drugs	\$331	\$331	\$0	0.00%
Average cost sharing for FDA-approved non-GLP-1 weight management drugs	\$58	\$46	-\$12	-21.12%
Number of enrollees receiving bariatric surgery	6,753	6,758	5	0.08%
Average unit cost of bariatric surgery	\$29,522	\$29,522	\$0	0.00%
Average cost sharing for bariatric surgery	\$4,044	\$4,043	-\$1	-0.03%
Number of enrollees receiving IBT for weight loss	27,251	27,264	13	0.05%
Average unit cost of IBT	\$500	\$500	\$0	0.00%
Average cost sharing for IBT	\$1	\$1	\$0	5.57%
Expenditures				
<i>Premiums</i>				
Employer-sponsored (b)	\$60,464,864,000	\$61,512,099,000	\$1,047,235,000	1.73%
CalPERS employer (c)	\$6,427,894,000	\$6,512,064,000	\$84,170,000	1.31%
Medi-Cal (excludes COHS) (d)	\$30,695,338,000	\$30,695,338,000	\$0	0.00%
<i>Enrollee Premiums (expenditures)</i>				
Enrollees, individually purchased insurance	\$22,369,982,000	\$22,784,835,000	\$414,853,000	1.85%
Outside Covered California	\$5,010,675,000	\$5,090,326,000	\$79,651,000	1.59%
Through Covered California	\$17,359,307,000	\$17,694,509,000	\$335,202,000	1.93%
Enrollees, group insurance (e)	\$19,150,165,000	\$19,477,375,000	\$327,210,000	1.71%
<i>Enrollee out-of-pocket expenses</i>				
Cost-sharing for covered benefits (deductibles, copayments, etc.)	\$14,553,460,000	\$14,809,366,000	\$255,906,000	1.76%
Expenses for noncovered benefits (f) (g)	\$0	\$0	\$0	0.00%
Total Expenditures	\$153,661,703,000	\$155,791,077,000	\$2,129,374,000	1.39%

Source: California Health Benefits Review Program, 2023.

Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, and Medi-Cal.

(b) In some cases, a union or other organization. Excludes CalPERS.

(c) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.1% are state retirees, state employees, or their dependents. About one in five (22.5%) of these enrollees has a pharmacy benefit not subject to DMHC. However, CHBRP has projected an impact for those enrollees.

(d) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. In addition, CHBRP estimates that it's likely that there would also be a proportional increase of \$0 million for Medi-Cal beneficiaries enrolled in COHS managed care.

(e) Enrollee premium expenditures include contributions by enrollees to employer (or union or other organization)-sponsored health insurance, health insurance purchased through Covered California, and any contributions to enrollment through Medi-Cal to a DMHC-regulated plan.

(f) 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 would be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

(g) 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; COHS = County Operated Health Systems; DMHC = Department of Managed Health Care; GLP = glucagon-like peptide; IBT = intensive behavioral therapy.

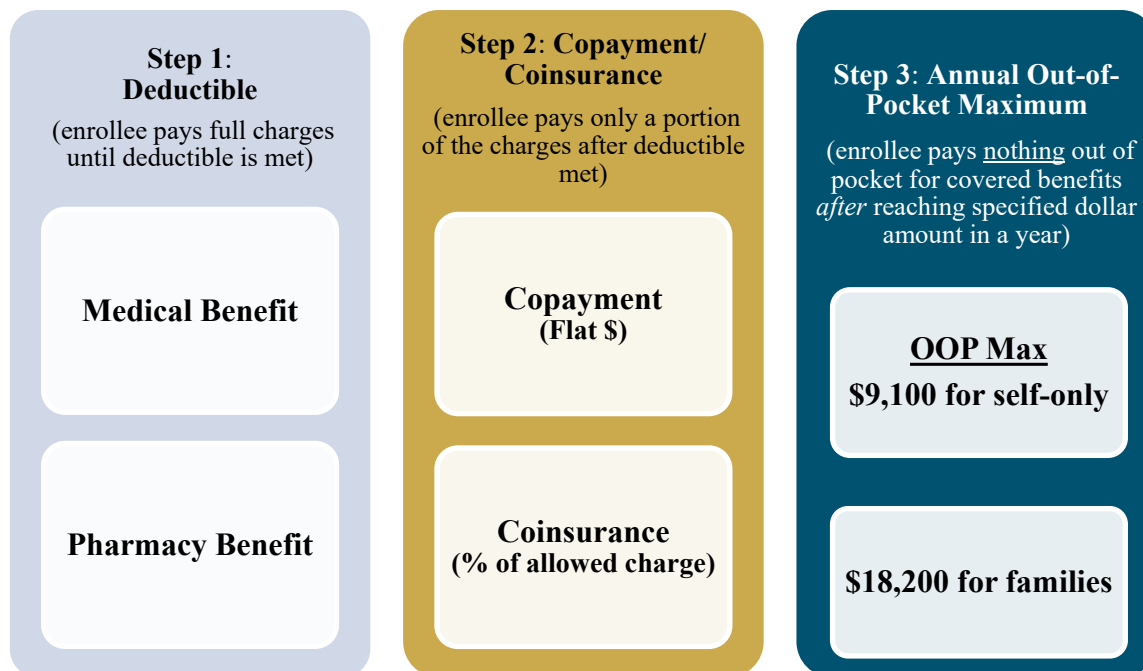
APPENDIX D COST SHARING

This appendix provides an overview of the cost-sharing used for health insurance benefits, including prescription drugs.

Payment for use of covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Common cost-sharing mechanisms include copayments, coinsurance, and/or deductibles (but do not include premium expenses⁶⁶). There are a variety of cost-sharing mechanisms that can be applicable to covered benefits (Figure 7). Some health insurance benefit designs incorporate higher enrollee cost sharing in order to lower premiums. Reductions in allowed copayments, coinsurance, and/or deductibles can shift the cost to premium expenses or to higher cost sharing for other covered benefits.⁶⁷

Annual out-of-pocket maximums for covered benefits limit annual enrollee cost sharing (medical and pharmacy benefits). After an enrollee has reached this limit through payment of coinsurance, copayments, and/or deductibles, insurance pays 100% of the covered services. The enrollee remains responsible for the full cost of any tests, treatments, or services that are not covered benefits.

Figure 7. Overview of the Intersection of Cost-Sharing Methods Used in Health Insurance



Source: California Health Benefits Review Program, 2023; CMS, 2022.

Note: Steps 1 and 2 are not mutually exclusive. Under certain circumstances (i.e., preventive screenings or therapies), enrollees may pay coinsurance or copayments prior to their deductible being met; also, copayments and coinsurance may be applied against the deductible in some circumstances. The figure assumes that the enrollee is in a plan with a deductible. If no deductible, then enrollee pays a coinsurance and/or a copayment beginning with the first dollar spent (Step 2).

The annual out-of-pocket maximums listed in Step 3 increase each year according to methods detailed in CMS' Notice of Benefit and Payment Parameters (CMS, 2022).

Key: OOP Max = annual out-of-pocket maximum.

⁶⁶ Premiums are paid by most enrollees, regardless of their use any tests, treatments, or services. Some enrollees may not pay premiums because their employers cover the full premium, they receive premium subsidies through the Covered California, or they receive benefits through Medi-Cal.

⁶⁷ Plans and policies sold within Covered California are required by federal law to meet specified actuarial values. The actuarial value is required to fall within specified ranges and dictates the average percent of health care costs a plan or policy covers. If a required reduction in cost sharing impacts the actuarial value, some number of these plans or policies might have to alter other cost-sharing components of the plan and/or premiums in order to keep the overall benefit design within the required actuarial value limits.

High deductible health plans

Both DMHC-regulated plans and CDI-regulated policies may be designated high deductible health plans (HDHPs).⁶⁸ HDHPs are a type of health plan with requirements set by federal regulation.⁶⁹ As the name implies, these plans include a deductible, but they are not allowed to have separate medical and pharmacy deductibles. For the 2023 plan year, the Internal Revenue Service (IRS) defines an HDHP as any plan with a deductible of at least \$1,500 for an individual and \$3,000 for a family.⁷⁰ Annual out-of-pocket expenses for coverage of in-network tests, treatments, and services, which would result from cost sharing⁷¹ applicable after the deductible is met, are not allowed to be more than \$7,500 for an individual and \$15,000 for a family.⁷²

Health Savings Account qualified HDHPs

To be eligible to establish a Health Savings Account (HSA) for taxable years beginning after December 31, 2003,⁷³ (and so to be eligible to make tax-favored contributions to an HSA) a person must be enrolled in an HSA-qualified HDHP.

In order for an HDHP to be HSA qualified, it must follow specified rules regarding cost sharing and deductibles, as set by the IRS. Generally, an HSA-qualified HDHP may not provide benefits for any year until the deductible for that year is satisfied, but federal law provides a safe harbor for the absence of a deductible applicable to preventive care.⁷⁴ Therefore an HSA-qualified HDHP may cover preventive care benefits without any deductible or with a deductible below the minimum annual deductible, but is not required to do so for a specified list of preventive services. The list of preventive services for which application of a deductible is not required includes treatments for chronic conditions.⁷⁵

Allowed Cost Amounts for Medical Services

Insurers usually negotiate how much they will pay for the costs of covered health care services with health care providers and suppliers (CBPP, 2018). These negotiated amounts are known as the “allowed cost amount.” Health care providers, including hospitals and physicians, participating in a plan’s network agree to accept these payment amounts when an enrollee covered by the plan uses covered services. The cost-sharing charges the enrollee owes (for example, a 20% coinsurance rate) are based on this allowed cost amount. If an enrollee uses a service that is not covered or sees a provider that is not within the insurer’s network, the overall charge, including an enrollee’s cost sharing, could be higher than the allowed amount.

⁶⁸ For enrollment estimates, see CHBRP’s resource *Deductibles in State-Regulated Health Insurance for 2023*, available at https://chbrp.org/other_publications/index.php.

⁶⁹ HealthCare.gov, Glossary: High Deductible Health Plan (HDHP). Available at www.healthcare.gov/glossary/high-deductible-health-plan/#:~:text=For%202019%2C%20the%20IRS%20defines,or%20%2413%2C500%20for%20a%20family. Accessed March 5, 2021.

⁷⁰ IRS Revenue Procedure 2022-24, available at www.irs.gov/pub/irs-drop/rp-22-24.pdf

⁷¹ Such as copays and coinsurance applicable to the covered test, treatment, or service.

⁷² There is no annual out-of-pocket expenses limit for coverage of out-of-network tests, treatments, and services.

⁷³ Section 1201 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, added section 223 to the Internal Revenue Code.

⁷⁴ For more information on screening services, see Notice 2004-23, 2004-15 I.R.B. 725, available at www.irs.gov/irb/2004-15_IRB#NOT-2004-23.

For additional guidance on preventive care, see Notice 2004-50, 2004-2 C.B. 196, Q&A 26 and 27, available at www.irs.gov/irb/2004-33_IRB#NOT-2004-50; and Notice 2013-57, 2013-40 I.R.B. 293, available at IRS.gov/pub/irs-drop/n-13-57.pdf.

⁷⁵ For information on preventive care for chronic conditions, see Notice 2019-45, 2019-32 I.R.B. 593, available at www.irs.gov/pub/irs-drop/n-19-45.pdf.

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CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM COMMITTEES AND STAFF

A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing 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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