# California Health Benefits Review Program

## Analysis of California Senate Bill 221
## HIV Associated Lipodystrophy

A Report to the 2017–2018 California State Legislature April 3, 2017

CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

# Key Findings:

## Analysis of California Senate Bill 221 HIV Associated Lipodystrophy

Summary to the 2017–2018 California State Legislature, April 3, 2017

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

## AT A GLANCE

The version of California Senate Bill 221 analyzed by CHBRP would require coverage for treatments related to HIV associated lipodystrophy. In 2018, 24 million enrollees in plans or policies regulated by DMHC or CDI will have health insurance that would be subject to SB 221

1. **Benefit coverage.** Postmandate, 5% of these enrollees would gain mandate-compliant benefit coverage.
2. **Utilization.** Postmandate, the number of enrollees using one or more treatments is expected to rise from 385 to 400.
3. **Expenditures.** Premiums and enrollee expenses for covered benefits (cost-sharing, deductibles, etc.) would be increase by $115,000 (0.0001%).
4. **Medical effectiveness.** A number of treatments provide short-term relief. However, their long-term effectiveness varies across treatments
5. **Public health.** New users may experience some short-term improvements in health and quality of life, but it is unclear whether these improvements will last or fade.
6. **Long-term impacts.** As the prevalence of HIV associated lipodystrophy is likely to continue to decline, the utilization, expenditure, and health outcome impacts projected for the first year after implementation are also expected to decrease.
7. **Medi-Cal** – in addition to impacting the health insurance of the 7.8 million Med-Cal beneficiaries enrolled in a DMHC-regulated plans (impacts included in the bullets above), SB 221 may similarly affect the health insurance of the additional 3.0 million Californians associated with either the Medi-Cal FFS program or COHS managed care.

## BACKGROUND

Lipodystrophy associated with human immunodeficiency virus (HIV)[1] describes abnormal changes in body fat. It may involve either or both:

- Lipoatrophy — abnormal fat loss in the face, limbs, and buttocks. Facial lipoatrophy is the most common presentation. Lipoatrophy is distinct from HIV-related wasting, which is a general loss of fat and lean muscle tissue.

- Lipohypertrophy — abnormal fat deposition in the abdomen, breasts (in both men and women), upper back and shoulders (“buffalo hump”), and around the neck (“horse collar”).

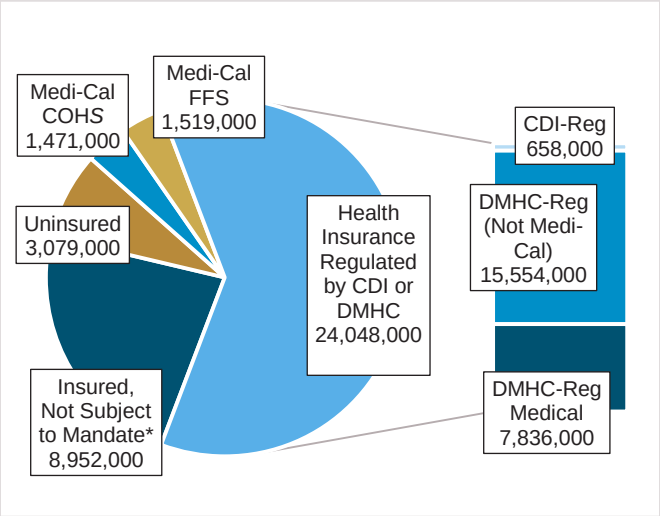
Some early antiretroviral therapy (ART) drugs — which have not been recommended or commonly used in California since 2003 — are strongly correlated with HIV associated lipodystrophy. The condition has declined along with use of those early ART drugs. CHBRP estimates current prevalence of HIV associated lipodystrophy among the HIV+ enrollees to be less than 1%.

## BILL SUMMARY

SB 221 would require plans and policies regulated by either the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI) to cover treatments (medical and drug) to correct, repair, or ameliorate effects of HIV associated lipodystrophy. In 2018, approximately 24 million Californians will be enrolled in or policies or plans regulated by CDI or DMHC (including 7.8 million Medi-Cal beneficiaries).

[1] Refer to CHBRP’s full report for full citations and references.

**Figure 1.** Health Insurance in CA and SB 221




*Source:* CHBRP 2017
*Notes:* *Medicare beneficiaries, enrollees in self-insured products, etc.

**Although the bill language is unclear**, CHBRP has assumed for this analysis that SB 221 would not prohibit generally applicable utilization management techniques, including application of medical necessity criteria, requiring prior authorization, or exclusion from coverage of treatments deemed to be experimental or investigational.

# IMPACTS

## Medical Effectiveness

SB 221 would require coverage for drug and medical/surgical treatments.

CHBRP's medical effectiveness analysis included several medical/surgical l treatments. CHBRP found:

- A *preponderance* of evidence that fillers increase facial fat (i.e., reduce the visible effects of facial lipoatrophy) and limited evidence that their effects persist for 2 to 5 years;
- *Limited* evidence that autologous fat transplantation increases facial fat, but *insufficient* evidence to determine how long the effect persists; and
- *Insufficient* evidence to determine whether fillers improve outcomes for persons with HIV associated buttock lipoatrophy.
- *Insufficient* evidence to determine whether liposuction affects outcomes for persons with breast hypertrophy or gynecomastia.
- *Insufficient* evidence to determine whether lipectomy or deoxycholic acid injections improve outcomes for persons with the form of lipohypertrophy referred to as "buffalo hump."

CHBRP's medical effectiveness analysis included several drug treatments. CHBRP found:

- A *preponderance* of evidence that switching ART to exclude stavudine or zidovudine, two drugs that are no longer routinely prescribed in California, increases facial and limb fat.
- A *preponderance* of evidence that metformin reduces body mass index and waist-to-hip ratio, but may increase the likelihood of lipoatrophy;
- A *preponderance* of evidence that tesamorelin (Egrifta) reduces abdominal visceral fat, preserves abdominal subcutaneous fat, and increases lean body mass but insufficient evidence of benefits and risks associated with long-term treatment.
- A *preponderance* of evidence that growth hormone reduces visceral fat. However, there is *conflicting* evidence as to whether effects persist after treatment ends. Using growth hormone is associated with increased risk of developing diabetes.

## Benefit Coverage, Utilization, and Cost

The analysis considers SB 221's aggregate impacts on the medical/surgical and drug treatments most likely to be impacted by changes in benefit coverage.

### Benefit Coverage

Postmandate, the percentage of enrollees with benefit coverage fully compliant with SB 221 would rise from 95% to 100%.

### Utilization

Postmandate, among the 24 million enrollees in DMHC-regulated plans and CDI-regulated policies, CHBRP estimates that an additional 15 (and so a total of 400)

enrollees would use of treatments for HIV associated lipodystrophy.

### Expenditures

Postmandate, as a result of the changed benefit coverage among the 24 million enrollees in DMHC-regulated plans and CDI-regulated policies, premium expenditures would increase by $115,000 (0.0001%).

As would be expected, some enrollees using newly compliant benefit coverage would incur some cost sharing, Although enrollees with newly compliant benefit coverage may have paid for some treatments during the baseline period, CHBRP cannot estimate the frequency with which such situations may have occurred and so cannot estimate the total expense for such situations. Postmandate, such expenses would be gone, though enrollees with newly compliant benefit coverage might, postmandate, pay for some treatments for which coverage is denied (e.g., through utilization management review). Some enrollees who always had compliant benefit coverage might also pay for some treatments. Again, CHBRP cannot estimate the frequency of such situations.

### Medi-Cal

To the extent permitted by federal law, SB 221 would require the same benefit coverage for all Medi-Cal beneficiaries, including those with health insurance through County Organized Health System (COHS) managed care and those associated with the fee-for-service (FFS) program. Therefore, in addition to the Medi-Cal beneficiaries enrolled in DMHC-regulated plans, SB 221 could affect benefit coverage for another 3 million Med-Cal beneficiaries who are either enrolled in County Organized Health System (COHS) managed care or engaged in Medi-Cal's fee-for-service (FFS) system. In addition to the expected increase of $104,000 in premiums CHBRP is estimating for the 7.8 million Medi-Cal beneficiaries enrolled in DMHC-regulated plans (a figure which represents a 0.0004% increase in premiums), it seems reasonable to assume that a population proportional increase of $19,455 would occur for the 1.5 million beneficiaries enrolled in COHS managed care. It seems likely that a similar impact would occur for the 1.5 million beneficiaries with health insurance through the FFS program (though the exact amount is unknown).

### CalPERS

CHBRP estimates no measurable change in premium impacts for CalPERS.

### Number of Uninsured in California

CHBRP would expect no measurable impact of SB 221 on the number of uninsured persons.

## Public Health

In the first year, postmandate, CHBRP would expect some increase in use of treatments by about 15 enrollees in DMHC-regulated plans and CDI-regulated policies. For those persons, there may be some improvements in health and quality of life.

## Long-Term Impacts

Because the prevalence of HIV associated lipodystrophy appears to have declined along with use of early antiretroviral drugs there may be a shrinking number of persons for whom the treatments are medically necessary. This suggests that the utilization and expenditure impacts projected in this analysis for the first year after implementation of SB 221 would decline over time.

Furthermore, although treatments may, to varying degrees, provide short-term relief from the burden of symptoms, there is little or no evidence of long-term effectiveness. The lack of long-term effectiveness may both decrease utilization over time and may suggest that initial improvements in health outcomes may fade.

## Essential Health Benefits and the Affordable Care Act

Because medically necessary treatments for HIV associated lipodystrophy are generally covered by health insurance in California, including the state's benchmark plan, it seems that SB 221 would not exceed the definition of essential health benefits (EHBs) in California. **However, the possibility that the language of the bill would prohibit generally applicable utilization management techniques, including application of medical necessity criteria, or exclusion from coverage of treatments deemed to be experimental or investigational makes it unclear whether the bill would exceed EHBs.**