Key Findings

Analysis of California Senate Bill 1452 Biological Products

Summary to the 2019–2020 California State Legislature, May 21, 2020

AT A GLANCE

The version of California Senate Bill (SB) 1452 analyzed by CHBRP states that *if* health plans and policies provide coverage for reference biologics or the respective biosimilars under the medical benefit, plans and policies cannot limit which manufacturer's products are to be used when medically necessary.

1. CHBRP estimates that, in 2020, of the 21.7 million Californians enrolled in state-regulated health insurance, 100% of them will have insurance subject to SB 1452, including Californians in Medi-Cal managed care plans.
2. **Benefit coverage.** Approximately 68% of enrollees enrolled in commercial plans and policies, 72% of enrollees in CalPERS plans, and 0% of enrollees in Medi-Cal managed care plans have coverage that is fully compliant with SB 1452 at baseline.
3. **Utilization.** Due to lack of data, CHBRP is unable to estimate utilization of reference biologics and their biosimilars.
4. **Medical effectiveness findings:**
   a. *Limited evidence* that that biosimilars covered under the medical benefit are as safe as the reference biologics due to a lack of published studies of some biosimilars.
   b. *Insufficient evidence* that prior authorization and step therapy affect utilization of reference biologics and their biosimilars or health outcomes.
5. **Public health.** The public health impact of SB 1452 is unknown due to insufficient evidence regarding the impact of prior authorization and step therapy protocols on the utilization and cost of biologics or biosimilars. Thus, the impact of SB 1452 on disparities are also unknown.

CONTEXT

Biologics, or biological products, are preparations made from living organisms used to prevent, diagnose, treat, and cure a wide range of diseases and medical conditions.[1] Common examples include influenza and shingle vaccines, Avastin, and Humira. Most biologics are administered through intravenous infusion or subcutaneous or intramuscular injection. Those that require intravenous infusion are administered by a health professional and may be covered under an enrollee's medical benefit. Subcutaneous biologic injections may be self-administered by the patient with approval from a provider. Newer biologics are also administered through inhalers.

A biosimilar, or follow-on biologic, is a biologic with a highly similar structure and function to a reference product that does not demonstrate clinically meaningful differences in terms of purity, chemical identity, and bioactivity. The FDA approved the first biosimilar in March 2015. While biosimilars are versions of brand-name products, they are not the same as generic medications because they are not exact replicas of the reference product.

Biologics and biosimilars treat a wide range of conditions. Breast cancer, Non-Hodgkin's lymphoma, and numerous other types of cancers are some of the more common conditions treated with biologics typically covered under the medical benefit.

BILL SUMMARY

If health plans and policies provide coverage for "biological products" or the respective biosimilars under the medical benefit, SB 1452 states that plans and policies cannot limit which manufacturer's biological products or biosimilars are to be used when medically necessary. This provision is specific to physician- or clinician-administered biological products or the respective biosimilars.

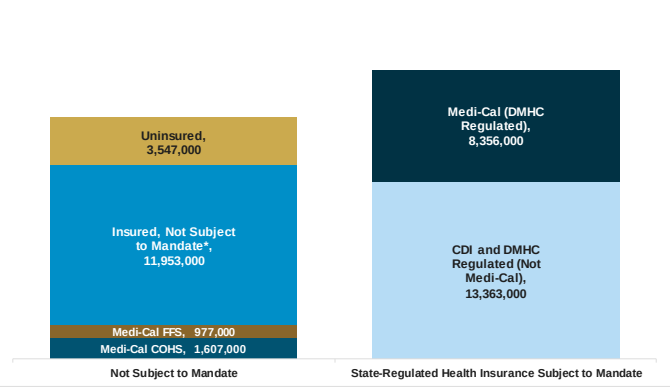
SB 1452 also prohibits plans and policies from requiring prior authorization or step therapy requirements that limit which manufacturer's biological products or the

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

respective biosimilars are to be administered by a physician or clinician to an enrollee.

SB 1452 only applies to reference biologics and biosimilars covered under the medical benefit. SB 1452 would not affect coverage for biologics and biosimilars that are covered under the pharmacy benefit. Additionally, while prior authorization and step therapy are prohibited when these policies require clinicians to use one biologic or biosimilar over another equivalent product, SB 1452 does not prohibit prior authorization or step therapy related to medical necessity or clinical appropriateness of a medication.

Figure A. Health Insurance in CA and SB 1452



Source: California Health Benefits Review Program, 2020.

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

IMPACTS

Benefit Coverage, Utilization, and Cost

CHBRP provides a qualitative discussion of the potential impacts to benefit coverage, utilization, and cost because CHBRP's quantitative data sources do not include data on any of the biosimilars that entered the market after 2017. CHBRP provides in this section an overview of baseline compliance with SB 1452 based on CHBRP's survey of health insurance plans and policies and a short discussion regarding the potential utilization and cost impacts of the bill based on the literature.

Benefit Coverage

Approximately 68% of enrollees in commercial plans and policies, 72% of enrollees in CalPERS plans, and 0% of enrollees in Medi-Cal managed care plans have coverage that is fully compliant with SB 1452 at baseline. Full compliance was defined as being compliant for all of the following three provisions: (1) coverage of all physician- and clinician-administered biosimilars and their associated reference biologic[2], (2) no prior authorization for the covered reference biologics and its biosimilars related to medication choice, and (3) no step therapy for the covered reference biologics and its biosimilars related to medication choice. Plans and policies could still have prior authorization and step therapy requirements for medical necessity as long as the requirements were applied equally to all covered reference biologics and biosimilars.

Postmandate, 100% of enrollees would have coverage fully compliant with SB 1452.

Prior Authorization and Step Therapy

While Medi-Cal managed care plans have greater coverage for the reference biologics and biosimilars (86% of enrollees in such plans have compliant coverage based on coverage of the medications) compared to enrollees in commercial or CalPERS plans and policies, coverage for the majority of enrollees in Medi-Cal managed care plans includes prior authorization to access certain medications. Thus, prior authorization was the main driver of noncompliance with SB 1452 at baseline for enrollees in Medi-Cal managed care plans. In contrast, enrollees in commercial plans and policies have the lowest levels of coverage of the medications (71% of enrollees in commercial plans and policies were deemed compliant based on coverage) for all reference biologics and biosimilars compared to enrollees in CalPERS and Medi-Cal managed care plans, but the vast majority of enrollees were in plans and policies that have no prior authorization requirements (86%) to access certain medications that are covered. Most enrollees in CalPERS plans have coverage with no prior authorization to access certain medications (96% compliance) and only a share of enrollees have coverage that was noncompliant based on coverage of medications and step therapy.

Baseline Utilization and Per-Unit Cost

Due to lack of available data, CHBRP is unable to determine utilization of reference biologics and their biosimilars.

In contrast to small molecule generic medications (i.e., medications that contain the same chemical substance as a branded medication), which can be upwards of 80% less expensive than their brand-name counterparts, biosimilars are anywhere between 15% and 40% less expensive than their biologic counterparts. Some

[2] Plans and policies are not required to cover all biologics and biosimilars, but if at least one reference biologic or the biosimilar is covered, all medications within that specific medication line need to be covered in order to be compliant.

enrollees are required to contribute a coinsurance for the medication that was administered to them in office, along with a copay or coinsurance for the office visit. The medication coinsurance amount is calculated based on the list price of the medication, which is the price usually published by the manufacturer and is available to the public.

Potential Postmandate Changes in Utilization and Cost

CHBRP lacks data needed to predict how SB 1452 would change utilization of biologics and biosimilars and how this would impact expenditures and enrollee out-of-pocket expenses. Apart from the lack of data, CHBRP concludes that due to the high degree of uncertainty in how the various stakeholders (health plans and insurers, providers, enrollees) impacted by this bill would react, the overall impact of this bill on utilization and expenditures is unknown.

- Health plans and insurers: While biosimilars are often listed at a discounted price in comparison to reference biologics, arrangements made by pharmacy benefit managers to secure rebates and other concessions that reduce the cost of reference biologics for payers may have limited the uptake of biosimilars. With SB 1452, plans and policies would not be able to explicitly prefer a reference biologic or a particular biosimilar over another. However, it is possible plans and payers could limit incentives to use the most expensive biologic products in other ways.

- Providers: While it is possible providers would shift towards preferring the lowest cost biosimilar for their patients, it is also possible providers opt to use more expensive products that would be more profitable to their practices.

- Enrollees: By prohibiting preference of one reference biologic or its biosimilar over another by health plans and insurers, SB 1452 could increase utilization of biosimilars. If an increased number of lower-cost biosimilars are utilized, enrollee cost sharing could be reduced. Enrollees may prefer lower-cost biosimilars over more expensive reference products. However, should providers switch to prescribing the reference biologic over its biosimilar, cost sharing for enrollees could increase or remain the same.

Medical Effectiveness

CHBRP assessed the safety of physician- and clinician-administered biosimilars (i.e., those typically covered under the medical benefit) compared to their reference biologics and the effect of prior authorization and step therapy requirements on utilization of these reference biologics and biosimilars and health outcomes.

There is limited evidence[3] that physician- and clinician-administered biosimilars are as safe as their reference biologics. CHBRP considered the evidence limited because most of the studies that CHBRP identified addressed reference biologics/biosimilars used to treat inflammatory diseases; few published studies addressed reference biologics/biosimilars used to treat cancer. Across the 11 articles included in the *Medical Effectiveness* section of the analysis, six examined the safety of biosimilars among mixed populations of people who were previously treated with a reference biologic or were not previously treated and five studied the safety of biosimilars among patients who switched from reference biologics. Most of these studies assessed the safety of infliximab (Remicade) biosimilars (most notably CT-P13, or infliximab-dyyb/Inflectra), but other studied biosimilars included filgrastim (Neupogen) biosimilars, trastuzumab (Herceptin) biosimilars, and rituximab (Rituxan) biosimilars. The studies consistently found that rates of adverse events were similar between patients treated with reference biologics and biosimilars.

There is insufficient evidence[4] that prior authorization and step therapy affect biologic/biosimilar utilization or health outcomes. CHBRP did not identify any studies that directly addressed this topic. A few studies address prior authorization or step therapy for reference biologics, but they do not examine the impact of these policies on utilization of biosimilars of these reference biologics or on health outcomes.

Public Health

Biologics and biosimilars treat a wide range of medical conditions and therefore the measurable health outcomes relevant to SB 1452 are dependent on both the treatment and condition in question. A significant change in utilization of these products could have an

[3] *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.
[4] *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.

impact on the physical health outcomes of enrollees being treated by them.

In the first year postmandate, the public health impact of SB 1452 is unknown due to insufficient evidence regarding the impact of prior authorization and step therapy protocols on the utilization and cost of biologics or biosimilars. Thus, the impact of SB 1452 on disparities are also unknown. Please note that the absence of evidence is not "evidence of no effect." It is possible that an impact — desirable or undesirable — could result, but current evidence is insufficient to inform an estimate.

Long-Term Impacts

CHBRP lacks the data necessary to make conclusive statements on long-term impacts. This is due to insufficient evidence related to use and impact of prior authorization and step therapy for these drugs, and insufficient data related to their costs and utilization. Research efforts on biologics and biosimilars will likely continue for the foreseeable future and may impact the prescription drug market. However, it is unknown how these changes may influence the impacts of SB 1452 in the long-term.

Essential Health Benefits and the Affordable Care Act

SB 1452 would not require coverage for a new state benefit mandate. Instead, SB 1452 modifies terms and conditions of already covered medications. Therefore, SB 1452 appears not to exceed the definition of EHBs in California.

At the time of this CHBRP analysis, there is substantial uncertainty regarding the impact of the COVID-19 pandemic on premium rates and health plan enrollment, including how the pandemic will impact healthcare costs in 2021. Because the variance of potential outcomes is significant, CHBRP does not take these effects into account as any projections at this point would be speculative, subject to federal and state decisions and guidance currently being developed and released. In addition, insurers', providers', and consumers' responses are uncertain and rapidly evolving to the public health emergency and market dynamic.