

Key Findings

Analysis of California Assembly Bill 2144 Step Therapy

Summary to the 2019–2020 California State Legislature, April 14, 2020



AT A GLANCE

For commercial/CalPERS enrollees, the version of California Assembly Bill 2144 analyzed by CHBRP would specify conditions for step therapy and prior authorization protocols when applied to a pharmacy benefit. AB 2144 exempts the health insurance of Medi-Cal beneficiaries enrolled in plans regulated by the Department of Managed Health Care (DMHC).

1. CHBRP estimates that of the 21.7 million Californians enrolled in state-regulated health insurance, 13.4 million of them will have insurance subject to AB 2144.
2. Benefit coverage. Commercial/CalPERS enrollees have near compliant benefit coverage, but for 1.1 million, AB 2144 would require step therapy exemptions for some new enrollees.
3. Utilization. No change for prior authorizations, but 544 more step therapy overrides (a 0.87% increase) would to be approved for commercial/CalPERS enrollees.
4. Expenditures. Total net annual expenditures would increase by \$721,000, or less than 0.01%, for commercial/CalPERS enrollees.
5. Medical effectiveness. There is insufficient evidence to determine whether step therapy or prior authorization protocols directly affect health outcomes, although there is a preponderance of evidence that step therapy reduces use of any medication for a condition. A decrease in medication use may be harmful if medication is essential for effective treatment of the condition.
6. Public health. No public health impact is expected regarding prior authorization, as commercial/CalPERS enrollee benefit coverage is already compliant. The public health impact of the more step therapy overrides is unknown due to insufficient evidence regarding the direct impact of such protocols on health outcomes. Please note that the absence of evidence is not evidence of no effect.

CONTEXT¹

A pharmacy benefit covers outpatient medications and generally involves a formulary, which generally indicates which drugs are preferred. Use of preferred drugs results in less cost sharing for the enrollee.

Step therapy or “fail-first” is a utilization management protocol that can be applied to one or more medications. Its purposes are to control costs, manage safety and medication compatibility, and enforce clinical guidelines and compliance with Food and Drug Administration (FDA) indications for use. It can require an enrollee to try and fail one or more medications prior to receiving coverage for the initially prescribed medication. Step therapy protocols usually require starting with a less expensive (generic) medication and may require starting with a less potent medication or dosage (graduating to more potent medications as necessary). Step therapy override requests follow a procedure by which a prescriber documents to the plan/insurer why an enrollee should be allowed to skip one or more of a step therapy protocol’s steps.

Prior authorization — also known as precertification, prior approval, or prospective review — is another utilization management protocol that can be applied to one or more medications. Its purposes are to control costs, ensure medication compatibility, enforce clinical guidelines and compliance with FDA indications for use, and protect patient health outcomes. Prior authorization also supports the formulary, as coverage for non-formulary medications generally requires prior authorization. Under prior authorization, providers must document the medical necessity of a prescription and obtain the plan/insurer’s approval before a pharmacy can fill the prescription.

Similar to other utilization management protocols, step therapy and prior authorization protocols, when applied to a pharmacy benefit, vary between plans and policies.

BILL SUMMARY

AB 2144 would address application of step therapy and prior authorization protocols to the coverage of outpatient prescription medications.

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

Regarding step therapy, AB 2144 would:

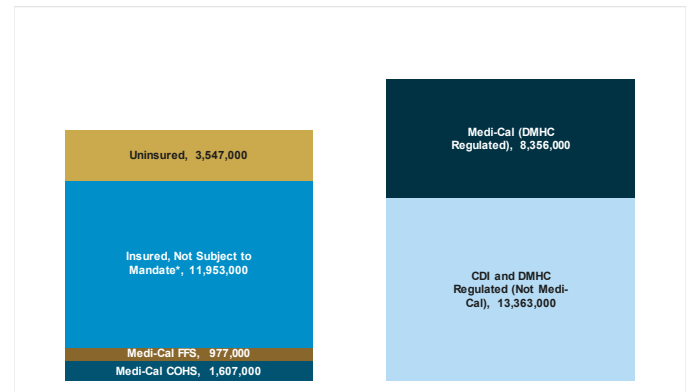
- Prohibit requiring new enrollees to repeat step therapy;
- Require use of a clinical peer (who was not involved in the initial decision) to review appeals;
- Allow an enrollee's designee, guardian, primary care physician, or health care provider to file an appeal of a denial of prior authorization or step therapy exception request; and
- Require granting exemption requests if:
 - The required medication is contraindicated or may cause an adverse reaction or physical/mental harm;
 - The required medication is expected to be ineffective (based on known characteristics of the enrollee and/or the medication);
 - The enrollee has tried: (1) the required medication, (2) another medication in the same class, or (3) another medication with the same mechanism and discontinued due to lack of effectiveness, diminished effect, or adverse event;
 - The required medication is not in the best interest of the enrollee, based on medical necessity; or
 - The enrollee is stable on a medication covered by their current or previous plan/policy.

Regarding step therapy and prior authorization, AB 2144 would:

- require approval/denial responses to exemption requests within 72 hours if nonurgent and within 24 hours if urgent. Nonresponse would be deemed an approval for the exemption request.

AB 2144 exempts the health insurance of Medi-Cal beneficiaries enrolled in plans regulated by the Department of Managed Health Care (DMHC) from these requirements.

Figure A. Health Insurance in CA and AB 2144



Source: California Health Benefits Review Program, 2020.

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

IMPACTS

Benefit Coverage, Utilization, and Cost

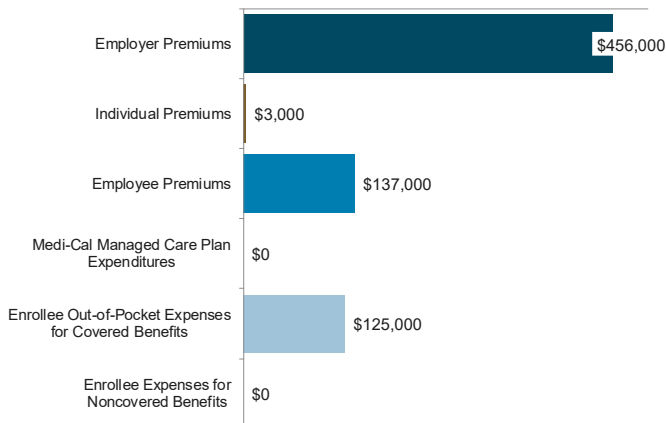
Approximately 91.7% of commercial/CalPERS enrollees in plans and policies regulated by DMHC and CDI have benefit coverage that is fully compliant with AB 2144's requirements. The remaining enrollees have benefit coverage compliant with AB 2144's other aspects, but require some new enrollees to repeat step therapy (which AB 2144 would prohibit). Postmandate, all commercial/CalPERS enrollees would have benefit coverage that is fully compliant with AB 2144.

Utilization

No change in the 1,493,526 prior authorizations for commercial/CalPERS enrollees would be expected for 2021, as related benefit coverage is already compliant with AB 2144. However, postmandate, CHBRP would expect the 544 more step therapy overrides (a 0.87% increase) to be granted to people who are newly enrolled in a commercial/CalPERS plan/policy in 2021 and ask to be exempt from repeating step therapy.

Expenditures

As noted in Figure B, AB 2144 would increase total net annual expenditures by \$721,000, or less than 0.01%, for commercial/CalPERS enrollees.

Figure B. Expenditure Impacts of AB 2144

Source: California Health Benefits Review Program, 2020.

Medi-Cal

As AB 2144 exempts the benefit coverage of Medi-Cal beneficiaries enrolled in DMHC-regulated plans from compliance, AB 2144 would have no impact on Medi-Cal.

CalPERS

AB 2144 is expected to have no impact on CalPERS enrollees, because all have benefit coverage compliant with AB 2144 at baseline.

Number of Uninsured in California

As impacts on expenditures are less than 1%, no measureable impact on the number of uninsured Californians is projected.

Medical Effectiveness

Evidence of effectiveness varies.

For step therapy:

- *Preponderance* of evidence suggests that step therapy protocols are associated with a decrease in use of initially prescribed medications and an increase in use of medications that people are required to try under step therapy protocols. Whether reduction in use benefits or harms consumers depends on the medication and the availability of other equally effective medications with similar side effects.

- *Preponderance* of evidence suggests that step therapy protocols reduce rates of initiation, continuation, and adherence to any prescription medication used to treat a disease or condition. Reduction in initiation, continuation, or adherence to any prescription medication for a disease or condition may be harmful if the medication is essential for effective treatment of the condition.
- There is *insufficient evidence* to determine whether step therapy protocols affect the effectiveness of treatment for diseases or conditions. The absence of evidence is not evidence of no effect. It is an indication that the impact of step therapy protocols on treatment effectiveness is unknown.
- There is *insufficient evidence* to determine whether step therapy protocols directly affect health outcomes. The absence of evidence is not evidence of no effect. It is an indication that the impact of step therapy protocols on health outcomes is unknown.

For prior authorization:

- There is *limited evidence* that prior authorization protocols reduce use of medications subject to these policies. Whether reduction in use benefits or harms consumers depends on the medication and the availability of other equally effective medications with similar side effects.
- There is *limited evidence* that prior authorization protocols increase use of other prescription medications. Whether increase in use of other medications benefits or harms consumers depends on the medication. If other medications are equally effective and have less severe side effects, increasing their use may be beneficial. On the other hand, increasing use of other medications may be harmful if they have more severe side effects.
- Evidence on the effect of prior authorization protocols on health outcomes is *insufficient*.

Public Health

In the first year postmandate, no public health impact is expected regarding prior authorization, as

commercial/CalPERS enrollee benefit coverage already complies with AB 2144.

The public health impact of the estimated additional 544 step therapy overrides in the first year postmandate is unknown due to insufficient evidence regarding the direct impact of such protocols on health outcomes. 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.

Essential Health Benefits and the Affordable Care Act

AB 2144 would alter the terms and conditions of existing benefit coverage, but would not require coverage for a

new benefit and so appears unlikely to exceed the definition of essential health benefits 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 health care 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 dynamics.