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Analysis of California Assembly Bill 2144 Step Therapy

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Analysis of California Assembly Bill 2144 Step Therapy

A Report to the 2019–2020 California State Legislature

April 14, 2020



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:

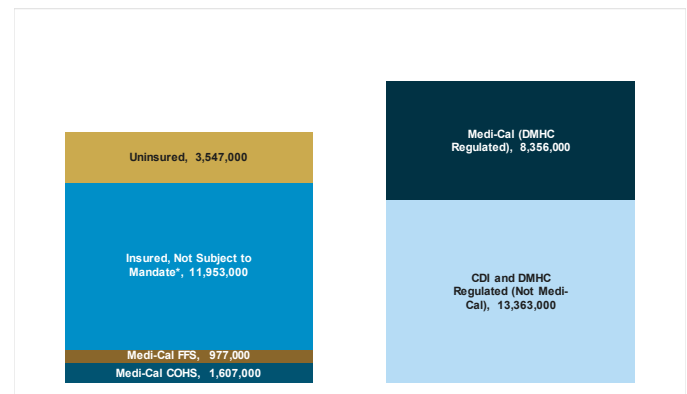
- Prohibit requiring new enrollees to repeat step therapy;
- Require use of a clinical peer (who was not involved in the initial decision) to review appeals;
- Allow an enrollee's designee, guardian, primary care physician, or health care provider to file an appeal of a denial of prior authorization 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

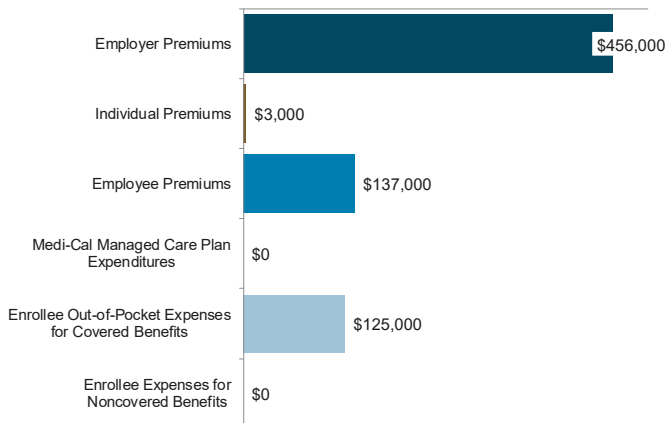
Approximately 91.7% of commercial/CalPERS enrollees in plans and policies regulated by DMHC and CDI have benefit coverage that is fully compliant with AB 2144's requirements. The remaining enrollees have benefit coverage compliant with AB 2144's other aspects, but require some new enrollees to repeat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

A Report to the California State Legislature

Analysis of California Assembly Bill 2144
Step Therapy

April 14, 2020

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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.

TABLE OF CONTENTS

Policy Context	1
Bill-Specific Analysis of AB 2144, Step Therapy and Prior Authorization.....	1
Analytic Approach	2
Interaction With Existing Requirements	2
Background Step Therapy Protocols and Prior Authorization	6
Step Therapy Protocols.....	6
Step Therapy Override Request	7
Prior Authorization.....	7
Disparities and Social Determinants of Health (SDoH) in Step Therapy Protocols and Prior Authorization.....	8
Medical Effectiveness	9
Research Approach and Methods.....	9
Methodological Considerations	10
Outcomes Assessed	10
Study Findings.....	11
Studies on the Impact of Step Therapy Protocols.....	12
Studies on the Impact of Prior Authorization.....	19
Summary of Findings	21
Benefit Coverage, Utilization, and Cost Impacts.....	23
Baseline and Postmandate Benefit Coverage	23
Baseline and Postmandate Utilization.....	26
Baseline and Postmandate Per-Unit Cost	26
Baseline and Postmandate Expenditures	27
Other Considerations for Policymakers	28
Public Health Impacts	33
Estimated Public Health Outcomes.....	33
Impact on Disparities.....	34
Long-Term Impacts	35
Long-Term Utilization and Cost Impacts	35
Long-Term Public Health Impacts.....	35
Appendix A Text of Bill Analyzed	A-1
Appendix B Literature Review Methods.....	B-1
Appendix C Cost Impact Analysis: Data Sources, Caveats, and Assumptions	C-1
References	
California Health Benefits Review Program Committees and Staff	
Acknowledgments	

LIST OF TABLES AND FIGURES

Table 1. AB 2144 Impacts on Benefit Coverage, Utilization, and Cost, 2021	ix
Table 2. Number of Medications Subject to Step therapy Protocols by Percent of Commercial/CalPERS Enrollees	25
Table 3. Number of Medications Subject to Prior Authorization Protocols by Percent of Commercial/CalPERS Enrollees	25
Table 4. Commercial/CalPERS Enrollees With Currently AB 2144–Compliant Benefit Coverage	26
Table 5. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2021	29
Table 6. Postmandate Per Member Per Month Premiums and Total Expenditures Impacts by Market Segment, California, 2021	31
Figure 1. Step Therapy Protocols on Utilization of Initially Prescribed Medications.....	13
Figure 2. Step Therapy Protocols on Utilization of Other Prescription Medications	14
Figure 3. Step Therapy Protocols on Initiation, Continuation, and Adherence to Prescription Medications	16
Figure 4. Step Therapy Protocols on Treatment Effectiveness	17
Figure 5. Step Therapy Protocols on Health Outcomes	18
Figure 6. Step Therapy Protocols on Utilization of Other Medical Care	18
Figure 7. Effects of Prior Authorization on Use of Medications Subject to Prior Authorization	19
Figure 8. Effects of Prior Authorization on Use of Other Prescription Medications	20
Figure 9. Effects of Prior Authorization on Health Outcomes	21
Figure 10. Baseline of Enrollee Benefit Coverage and Status of Mandate Compliance Under AB 2144...	24

Table 1. AB 2144 Impacts on Benefit Coverage, Utilization, and Cost, 2021

	Baseline	Postmandate	Increase/ Decrease	Percentage Change
Benefit coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	21,719,000	21,719,000	0	0.00%
Total enrollees with health insurance subject to AB 2144	13,363,000	13,363,000	0	0.00%
Total percentage of enrollees with coverage subject to AB 2144	62%	62%	0%	0.00%
Number of enrollees with outpatient prescription medication benefit fully compliant with AB 2144	12,250,000	13,363,000	1,113,000	9.09%
Percentage of enrollees with coverage for outpatient prescription medication benefit fully compliant with AB 2144	1,113,000	—	(1,113,000)	-100.00%
Utilization and unit cost				
Annual prior authorization requests granted	1,493,526	1,493,526	—	0.00%
Annual step therapy override requests granted	62,806	63,351	544	0.87%
Average per-unit cost of Rx subject to prior authorization	\$1,100.26	\$1,100.26	—	0.00%
Average per-unit cost differential of initially-prescribed medication and step therapy–required medication	\$579.17	\$579.17	—	0.00%
Expenditures				
Premiums (expenditures) by payer				
Private employers for group insurance	\$54,037,059,000	\$54,037,515,000	\$456,000	Less than 0.01%
CalPERS HMO employer expenditures (b) (c)	\$3,264,098,000	\$3,264,098,000	\$0	0.00%
Medi-Cal Managed Care Plan expenditures	\$29,218,820,000	\$29,218,820,000	\$0	0.00%
Enrollee premiums (expenditures)				
Enrollees for individually purchased insurance	\$15,689,758,000	\$15,689,761,000	\$3,000	Less than 0.01%
Individually purchased – outside exchange	\$4,412,875,000	\$4,412,875,000	\$0	0.00%
Individually purchased – Covered	\$11,276,883,000	\$11,276,886,000	\$3,000	Less than 0.01%

California				
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (c)	\$15,867,227,000	\$15,867,364,000	\$137,000	Less than 0.01%
Enrollee out-of-pocket expenses				
For covered benefits (deductibles, copayments, etc.) (f)	\$12,776,801,000	\$12,776,926,000	\$125,000	Less than 0.01%
For noncovered benefits (d) (e)	—	—	—	—
Total expenditures (g)	\$130,853,763,000	\$130,854,484,000	\$721,000	Less than 0.01%

Source: California Health Benefits Review Program, 2020.

Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.²

(b) Approximately 57.36% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five (20.5%) of these enrollees has a pharmacy benefit not subject to DMHC.³ CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

(c) Enrollee premium expenditures include contributions by employees to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal Managed Care.

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

(e) Although enrollees with newly compliant benefit coverage may have paid for some [tests/treatments/services] before [AB/SB #], CHBRP cannot estimate the frequency with which such situations may have occurred and therefore cannot estimate the related expense. Postmandate, such expenses would be eliminated, though enrollees with newly compliant benefit coverage might, postmandate, pay for some [tests/treatments/services] for which coverage is denied (through utilization management review), as some enrollees who always had compliant benefit coverage may have done and may continue to do, postmandate.

(f) Some shifts to higher tier drugs among the estimated additional step therapy overrides, and so some increase in copayments is possible but CHBRP cannot estimate a figure.

(g) Some enrollees who gain one of the estimated additional step therapy overrides may have been paying for the initially prescribed medication and so some increase in noncovered benefits expense may occur but CHBRP is not able to estimate a figure.

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

² For more detail, see *Estimates of Sources of Health Insurance in California for 2021*, available at http://chbrp.org/other_publications/index.php.

³ For more detail, see *Estimates of Pharmacy Benefit Coverage in California for 2021*, available at http://chbrp.org/other_publications/index.php.

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)⁴ conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 2144, step therapy, and prior authorization.

Bill-Specific Analysis of AB 2144, Step Therapy and Prior Authorization

The coverage enrollees have for outpatient prescription medications may be subject to utilization management protocols, such as step therapy and/or prior authorization. When applicable, step therapy protocols require that the enrollee first try and fail (one or more) alternatives before coverage becomes available for the initially prescribed medication. Prescribers can request an exemption, offering reasons why a particular patient should immediately be able to access coverage for the initially prescribed medication. When applicable, prior authorization requires that the prescriber provide the health plan with the clinical reasons why a particular patient should be able to access coverage for the prescribed medication before the health plan will authorize coverage.

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

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;
- 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.

⁴ CHBRP's authorizing statute is available at www.chbrp.org/faqs.php.

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.

The full text of AB 2144 can be found in Appendix A.

Relevant Populations

If enacted, AB 2144 would affect the health insurance of approximately 13.4 million enrollees (34% of all Californians). This represents 62% of the 21.7 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law — health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). If enacted, the law would affect the health insurance of commercial/CalPERS enrollees in DMHC-regulated plans and CDI-regulated policies but would exempt from compliance the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

Analytic Approach

Regarding step therapy and prior authorization protocols applied to one or more medications, it should be noted that many plans and insurers regulated by DMHC or CDI with commercial/CalPERS enrollees are accredited by the National Committee for Quality Assurance (NCQA). NCQA is a nonprofit organization originally sponsored by the Robert Wood Johnson Foundation that offers accreditation to health plans that follow specified guidelines (NCQA, 2020). The NCQA guidelines are similar, in a number of ways, to those proposed by AB 2144.⁵ The NCQA guidelines specify that for both step therapy exemption request and prior authorization request:

- Responses should generally be made within 24 or 72 hours, depending on the urgency of the situation, which is generally similar to what AB 2144 would require in terms of response times; and
- Requests should be reviewed by clinically appropriate practitioners and that reviewers should use information submitted by the enrollee's provider to take into account medical necessity, which is generally similar to what AB 2144 would require in terms of clinical peer review and generally similar to what AB 2144 would require in terms of most of the specifications regarding granting exemption requests.

AB 2144 would go further than the NCQA guidelines in requiring exemptions from step therapy for newly enrolled commercial/CalPERS enrollees who have already completed a step therapy process. Although many commercial/CalPERS enrollees have baseline compliance with this requirement as well, as noted in the *Benefit Coverage, Utilization, and Cost* section, not quite all do. The postmandate change in their benefit coverage drives the impacts described in this analysis.

Interaction With Existing Requirements

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

⁵ Personal communication, D. Stern, RxPerts, March 2020.

California Policy Landscape

DMHC-regulated plans and CDI-regulated insurers are required to respond to requests for prior authorization for medications within 72 hours for nonurgent requests and within 24 hours for urgent requests — and nonresponse is deemed to be approval.^{6,7}

CHBRP is aware of a number of current health insurance benefit mandates that might interact with compliance to AB 2144, although none would do so directly. Examples are listed by Health and Safety Code (H&S), with Insurance Code (IC) when applicable:

- *H&S1367.21/IC10123.195; prescription drugs: off-label use.* Mandate to cover “off-label” uses of federal Food and Drug Administration (FDA) approved drugs—uses other than the specific FDA-approved use—in life-threatening situations and in cases of chronic and seriously debilitating conditions—when a set of specified provisions regarding evidence are met.
- *H&S 1367.22; prescription drugs: coverage of previously covered drugs.* Mandate to cover prescription drugs if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition.

AB 2100 (Wood) Medi-Cal Pharmacy Benefits, a bill currently being considered by the California Legislature, would create some similar requirements regarding prior authorization step therapy protocols for the prescription medication coverage of all Medi-Cal beneficiaries.

Similar requirements in other states

Forty states and Washington, DC, (AZ, AR, CA, CO, CT, DE, D.C., FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NV, NH, NJ, NM, NY, NC, ND, OH, OK, TN, TX, UT, VT, VA, WA, and WV) have laws that govern prior authorization processes (AHIP, 2019a).

Nineteen states (AR, CA, CT, DE, IN, KY, LA, ME, MN, MS, MO, NM, NY, OH, OK, TX, VA, WV, and WI) have laws, that govern step therapy processes (AHIP, 2019b). The laws vary in terms of applicable requirements:

- **Step Therapy Limitations:** Fifteen states (AR, CA, CO, CT, DE, FL, IL, LA, MD, MN, MO, MT, ND, TX, and VT) have laws limiting the use of step therapy processes. Five states (DE, CO, IL, MO, and MT) have laws limiting the use of step therapy protocols for mental health and substance abuse treatments. Eight states (AR, CO, IL, LA, MD, MN, ND, and TX) have laws restricting the use of step therapy protocols for stage 4 metastatic cancer.
- **Step Therapy Protocols:** Eleven states (DE, IN, ME, MN, NY, NM, OH, OR, TX, VA, and WI) have laws implementing step therapy protocols, including clinical criteria and benchmarks.
- **Step Therapy Exceptions:** Nineteen states (AR, CA, CT, DE, IN, KY, LA, ME, MN, MS, MO, NM, NY, OH, OK, TX, VA, WV, and WI) have laws requiring health plans implement an exception process to step therapy protocols.

⁶ H&S Code 1367.241(a) and 1367.241 (b).

⁷ Insurance Code 10123.135(h).

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 AB 2144 may interact with requirements of the ACA as presently exists in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).^{8,9}

Any changes at the federal level may impact the analysis or implementation of this bill, were it to pass into law. However, CHBRP analyzes bills in the current environment given current law and regulations.

Essential Health Benefits

Nongrandfathered plans and policies sold in the individual and small-group markets are required to meet a minimum standard of benefits as defined by the ACA as essential health benefits (EHBs). In California, EHBs are related to the benefit coverage available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.^{10,11} CHBRP estimates that approximately 4 million Californians (10%) have insurance coverage subject to EHBs in 2021.¹²

States may require plans and policies to offer benefits that exceed EHBs.¹³ However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the qualified health plan.^{14,15} Health plans and policies sold outside of the health insurance marketplaces are not subject to this requirement to defray the costs. State rules related to provider types, cost sharing, or reimbursement methods would not meet the definition of state benefit mandates that could exceed EHBs.¹⁶

AB 2144's requirements regarding step therapy and prior authorization protocols would alter the terms and conditions of benefit coverage, but would not require new benefit coverage. Therefore, AB 2144 seems unlikely to exceed EHBs, and so unlikely to trigger the ACA requirement that the state defray the cost of additional benefit coverage for enrollees in qualified health plans (QHPs)¹⁷ in Covered California.

⁸ The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to QHPs 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.

⁹ 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.

¹⁰ CCIIO, Information on Essential Health Benefits (EHB) Benchmark Plans. Available at: <https://www.cms.gov/ccio/resources/data-resources/ehb.html>.

¹¹ H&SC Section 1367.005; IC Section 10112.27.

¹² CHBRP, *Estimates of Sources of Health Insurance in California in 2021*. Available at: www.chbrp.org/other_publications/index.php.

¹³ ACA Section 1311(d)(3).

¹⁴ 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: <https://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf>.

¹⁵ However, as laid out in the Final Rule on EHBs 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.

¹⁶ Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.

¹⁷ In California, QHPs are nongrandfathered small-group and individual market DMHC-regulated plans and CDI-regulated policies sold in Covered California, the state's online marketplace.

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.

BACKGROUND STEP THERAPY PROTOCOLS AND PRIOR AUTHORIZATION

This section provides context for the consideration of the impacts of AB 2144 by defining prior authorization and step therapy protocols.

Step Therapy Protocols

Step therapy or “fail-first” protocols are one type of several utilization management protocols¹⁸ applied to prescription medications by health plans and insurers to control costs, ensure medication compatibility, and manage safety. They are also an effective enforcement tool for clinical recommendations and guidelines. Health plans/insurers use them to apply clinical guidelines established by professional societies and other recognized organizations, such as the American College of Rheumatology and the National Comprehensive Cancer Network, respectively. In addition, step therapy protocols are used to enforce the FDA indication for use of a medication in relation to other medication therapy trials or failures. They require an enrollee to try and fail one or more medications prior to receiving coverage for the initially prescribed medication. Step therapy protocols usually recommend starting with a medication that is less expensive (generics) and/or has more “post-marketing safety experience” (PBMI, 2015). In addition, they sometimes require starting with a less potent medication or dosage, perhaps with fewer side effects, and graduating to more potent medications as necessary (e.g., from prescription Motrin to OxyContin to treat pain). Generally, more expensive medications are covered when the patient fails to respond to the step therapy–required medication (PBMI, 2018). Similar to other utilization management protocols, step therapy policies vary between plans/insurers. As formularies¹⁹ are updated based on the introduction of new treatments and medical guidelines, step therapy requirements are added to new medications as appropriate.

Step therapy protocols for some health plans/insurers require patients to try preferred brand-name medications after failing generic medications, prior to approving the initially-prescribed medication. Some of these preferred brand-name medications can include AB-rated generic equivalent medications, which are those that meet required bioequivalence standards established by the Food and Drug Administration. These AB-rated generic equivalent medications can sometimes have brand names. AB 2144 would not prohibit step therapies that require a patient to try an AB-rated generic equivalent medication²⁰ prior to covering the initially prescribed medication.

Patients may learn that an initially prescribed medication is subject to a step therapy under their current health plan/insurer when their prescription is electronically reviewed at the point-of-service (pharmacy) following submission for payment authorization. The review determines in real time whether the patient in question has already used the medication that the plan/insurer requires the patient to try before approving coverage of the initially prescribed medication. If coverage for the initially prescribed medication is declined under the step therapy, a pharmacist may substitute the AB-rated generic equivalent, if available.²¹ Alternatively, the prescriber may either reissue the prescription for the step therapy–required medication or appeal the decision directly to the health plan or insurer (requesting approval for a step therapy override). A patient always has the option to purchase the initially prescribed medication by paying the full cost out of pocket.

¹⁸ Other utilization management strategies used by health plans and insurers to manage the cost or safety of prescription medications include: age limits; quantity limits; gender limits; copayments/coinsurance; preferred medication lists, and prescription medication tiers (which increase enrollee contributions for more costly prescription medications classified in higher tiers).

¹⁹ A formulary is health plan or insurer’s list of preferred medications that are covered by the plan or policy, usually with some form of enrollee cost sharing.

²⁰ Food and Drug Administration (FDA). *Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)*. Silver Spring, Maryland: Center for Drug Evaluation and Research; 2020.

²¹ California Business & Professions Code, Division 2, Chapter 9, Section 4073.

Some examples of step therapies are listed below, demonstrating the requirement that an enrollee try and fail alternative medications prior to being approved for coverage of the initially prescribed medication:

- 1) An enrollee with rheumatoid arthritis (RA) initially prescribed a brand-name biologic (e.g., Humira or Enbrel), might be required to try and fail on a generic, nonbiologic medication (e.g., methotrexate) before accessing coverage for the biologic.
- 2) An enrollee with severe acne initially prescribed a brand-name medication (e.g., Avidoxy Kit, Minocin, Vibramycin) might be required to try and fail a generic version (e.g., doxycycline hydrate) before accessing coverage.
- 3) An enrollee with multiple sclerosis initially prescribed Aubagio (a brand-name medication) might be required to try and fail generic medications (e.g., Glatopa) and other brand-name medications (e.g., Copaxone or Rebif), before accessing coverage for Aubagio.

Step Therapy Override Request

Step therapy override requests follow a procedure by which a prescriber submits clinical documentation to the plan/insurer documenting why an enrollee should be allowed to skip one or more of a step therapy protocol's steps. Reasons prescribers use to justify such a step therapy override may include:

- 1) The enrollee has already tried step therapy–required medication(s) unsuccessfully (e.g., patient who had gone through step therapy with a medication under a previous health plan/insurer and has switched coverage).
- 2) The step therapy–required medication is contraindicated for that enrollee due to medication–medication interactions, medication–disease interactions, or medication allergy or intolerance.
- 3) The patient is already stable on a prescription medication on the health plan/insurer's formulary.

Step therapy override requests may take several days to be reviewed by the health plan or insurer.

Enrollees whose step therapy override requests are denied may purchase the initially prescribed medication by paying the full retail price out of pocket or may purchase the step therapy–required medication and only pay the plan/insurer's required copay/coinsurance (if applicable). If the plan/insurer grants the step therapy override, the enrollee will pay the designated copayment/coinsurance for that prescription.

Prior Authorization

Prior authorization — also known as precertification, prior approval, or prospective review — is another utilization management technique. Like step therapy protocols, they are used to enforce clinical guidelines from professional societies and organizations, and the FDA indication for use of specific medications. Pharmacy benefit managers and insurers/plans also use prior authorization as a safeguard to confirm that a patient's medications are compatible.

Common services that require prior authorization for benefit coverage include prescription medications, durable medical equipment, diagnostic radiology, surgical procedures, inpatient stays, and behavioral health treatments. AB 2144 pertains to only prior authorization of prescription medications.

In the context of AB 2144, prior authorization requires providers to establish eligibility and submit documentation demonstrating medical need to the plan/insurer for approval of coverage before a prescription is filled in order to qualify for payment. It is used as a tool to control costs and protect patient

health outcomes through the use of medications that have proven efficacy and safety (Allen and Ojong-Salako, 2015; AMCP, 2019). Prior authorization also supports the formulary, as coverage for nonformulary medications generally requires prior authorization.

Prior authorization policies vary between plans/insurers; as formularies are updated based on the introduction of new treatments and medical guidelines, prior authorization requirements are added to new medications as appropriate. Health plans and insurers analyze utilization patterns, clinical evidence, financial considerations, and government regulations and statutes to determine the type of care that requires prior authorization.

Patients may learn that the prescription written by their physician requires prior authorization from their health plan/insurer at the pharmacy when the pharmacist attempts to fill the prescription. Generally, prescription claims are initially denied under prior authorization so that the health plan or insurer can assess the therapy prior to the start of treatment. The pharmacist or patient then notifies the physician that prior authorization is required for the initially prescribed medication (PBMI, 2015). The physician or other health professional licensed to prescribe medications must then submit documentation for a prior authorization request of the initially prescribed medication to the health plan/insurer, which then completes a review to determine whether the prescription would be unnecessary or could cause dangerous interactions with other medications the patient is already using. The initially prescribed medication is then either approved or denied coverage. If denied, the patient has the option to purchase the initially prescribed medication by paying the full cost out of pocket or the prescriber can write a prescription for another medication in the same therapeutic class for which prior authorization is not required.

The prior authorization process can take several days. Health plans and insurers are required to respond to nonurgent prior authorization requests within 72 hours of receipt, and within 24 hours if urgent circumstances exist; otherwise the request is deemed to be granted.²² In 2017, physicians surveyed by the American Medical Association reported physicians and staff spending an average of 14.6 hours per week on this work (AMA, 2018). In an effort to decrease waiting times for patients and reduce administrative burden on prescribers, some prescribers have instituted the use of electronic prior authorization to assist prescribers in submitting requests in a more timely manner and to quickly receive the most recent information on formularies (Bhattacharjee et al., 2019; Birdsall et al., 2020).

Disparities²³ and Social Determinants of Health (SDoH)²⁴ in Step Therapy Protocols and Prior Authorization

SDoH include factors outside of the traditional medical care system that influence health status and health outcomes (e.g., income, education, geography, etc.). CHBRP found no studies on the impact of step therapy protocols, step therapy override requests, or the length of time for prior authorization on racial and ethnic disparities or SDoH. The extent to which AB 2144 would have an impact on these factors is therefore unknown due to a lack of evidence showing any effect of these utilization management techniques on them. 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.

²² California Health and Safety Code; California Insurance Code.

²³ 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).

²⁴ CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from CDC, 2014; and Healthy People 2020, 2019). See CHBRP’s SDoH white paper for further information:

http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, for health plans and policies that have step therapy protocols in place for prescription medications, AB 2144 would define circumstances in which a step therapy protocol override must be granted and would establish a deadline for approval or denial of step therapy overrides requests and prior authorization requests. AB 2144 also sets forth guidance for reviewing appeals of step therapy override requests.

Additional information about step therapy protocols and prior authorization is included in the *Background* section. The medical effectiveness review summarizes findings from evidence²⁵ regarding the impact of step therapy protocols and prior authorization on health outcomes and utilization of prescription medications and indirect effects on use of other health care services.

Research Approach and Methods

Studies of prior authorization and step therapy protocols and override procedures for prescription medications were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, and Business Source Complete. The following websites were also searched: the Agency for Healthcare Research and Quality, International Network of Agencies for Health Technology Assessment, National Health Service Centre for Reviews and Dissemination, National Institute for Health and Clinical Excellence, 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 2015 to present because CHBRP had previously conducted thorough literature searches on these topics in 2015 for AB 374 and in 2013 for AB 899. Of the 314 articles found in the literature review for this report on AB 2144, 21 were reviewed for potential inclusion in the report, and 14 studies were included in the medical effectiveness review for this report. The medical effectiveness review also presents findings from the 15 studies that were previously identified in the 2015 CHBRP AB 374 report.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.²⁶ Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

Key Questions

- 1) What are the impacts of step therapy protocols and prior authorization requirements on use of prescription medications?
- 2) What are the effects of step therapy protocols and prior authorization requirements on the effectiveness of treatment?
- 3) What are the impacts of step therapy protocols and prior authorization requirements on health outcomes?

²⁵ 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 on page 11 of the Medical Effectiveness Analysis and Research Approach document (posted at http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php), in the absence of fully applicable to the analysis peer-reviewed literature on well-designed randomized controlled trials (RCTs), CHBRP's hierarchy of evidence allows for the inclusion of other evidence.

²⁶ 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.

- 4) What are the indirect effects of step therapy protocols and prior authorization requirements on use of other health care services?

Methodological Considerations

Of the peer-reviewed studies CHBRP identified on the impact of step therapy protocols and prior authorization requirements, none were randomized controlled trials (RCTs), which are considered the “gold standard” of research. Most were nonrandomized studies with comparison groups that compared persons whose health plan or health insurance policy had a step therapy protocol or prior authorization requirement to persons whose health plan or health insurance policy did not implement such requirements. In some studies, persons in the intervention group (i.e., persons with health insurance subject to the step therapy protocol or prior authorization requirement) and the comparison group did not have similar demographic and socioeconomic characteristics prior to implementation of the requirement (see, for example, Suehs et al., 2013). In addition, 17 of the 29 studies were wholly or partially funded by pharmaceutical companies. A systematic review of studies of the impact of industry sponsorship on research findings concluded that sponsorship of studies of drugs or medical devices by manufacturers is associated with results and conclusions that are more favorable to their products (Lundh et al., 2012). Sponsorship may also affect findings from studies of step therapy protocols and prior authorization requirements aimed at reducing use of a manufacturer’s products.

Outcomes Assessed

Step Therapy Protocols

In 2015, CHBRP’s report on AB 374 identified one study on the impact of step therapy protocols on health outcomes. Momani and colleagues (2002) evaluated the impact of a step therapy protocol for nonsteroidal anti-inflammatory drugs (NSAIDs) implemented by West Virginia’s Medicaid program on health-related quality of life among persons with chronic pain (Momani et al., 2002).

CHBRP’s literature review for AB 2144 did not identify any new studies that directly evaluated the impact of step therapy protocols on health outcomes. In light of this, CHBRP reviewed studies that assess the effects of step therapy protocols on utilization of medications (e.g., number of prescriptions dispensed, proportion of days covered [PDC], and number of days’ supply of medication) and other medical services (e.g., emergency department visits). These studies may find a difference in utilization of prescription medications that may affect health outcomes. Some enrollees who are subject to step therapy may not obtain prescriptions for their medication or may delay or discontinue treatment. Treatment may not be initiated or may be delayed or discontinued because an enrollee may decide not to fill the prescription, or because the enrollee’s pharmacist and/or physician does not obtain authorization for the initially prescribed medication. If step therapy protocols are associated with a lower rates of medication use, they may lead to poorer health outcomes among people who need medications to manage their condition. Granting an exemption to step therapy may mitigate these adverse outcomes.

CHBRP’s report on AB 374 identified 15 studies of the impact of step therapy protocols on utilization of prescription medications and other health care services. In its review for AB 2144, CHBRP identified 5 additional studies on the impact of step therapy protocols on utilization of medications. One of these studies also examined the impact of step therapy protocols on the effectiveness of treatment. Boytsov et al. (2020) assessed the impact of step therapy and prior authorization for disease-modifying antirheumatic drugs (DMARDs) among people with rheumatoid arthritis or psoriatic arthritis on the effectiveness of treatment for rheumatoid arthritis and psoriatic arthritis and on medication adherence among people with these conditions. Suehs et al. (2015) evaluated the impact of a step therapy protocol on medication utilization among members of a commercial health plan with a step therapy protocol for guanfacine extended-release (GXR) among patients being treated for attention deficit hyperactivity disorder (ADHD). Null et al. (2016) evaluated changes in utilization of pregabalin (Lyrica®) in Medicare and commercial health plans. Kozma et al. (2015) evaluated the impact of step therapy on patients

receiving infusion biologics for immune disorders. Tang et al. (2017) evaluated the impact of step therapy for sitagliptin (Januvia®), an antidiabetic medication, among patients in three commercial health plans.

Prior Authorization

Because AB 2144 would require health plans/insurers to approve or deny nonurgent requests for prior authorization within 72 hours and urgent requests within 24 hours, CHBRP searched for literature on the impact of the length of time within which health plans/insurers must respond to prior authorization requests on health outcomes, the utilization of drugs, or other medical services, but CHBRP did not find any studies on these topics.

Given this lack of evidence, CHBRP reviewed studies that assess the effects of prior authorization requirements (regardless of the length of time a health plan has to make a decision) on health outcomes and utilization of drugs (e.g., number of prescriptions dispensed and days' supply of drugs).

CHBRP found one study on the impact of prior authorization on health outcomes. Cochran et al. (2017) examined the effects of prior authorization on opioid abuse and overdose among Medicaid enrollees who initiated a new opioid medication not used for addiction treatment.

CHBRP found eight studies on the impact of prior authorization on utilization of prescription medications. A systematic review by Mauri et al. (2020), which included three studies (Hartung et al., 2018, Keast et al., 2018, Morden et al., 2008), examined the impact of state Medicaid prior authorization policies on opioid prescription use. Barnett et al. (2018) examined the impact of prior authorization for long-acting opioid prescriptions among adults enrolled in commercial health plans. Andrews et al. (2019) used survey data from the National Drug Abuse Treatment System Survey to assess the relationship between utilization restrictions, including prior authorization, on buprenorphine availability at addiction treatment programs. In a systematic review (Stacey et al. [2017]; three studies) that examined the effectiveness of policies restricting access to pregabalin (Lyrica®), a treatment approved for fibromyalgia, neuropathic pain due to postherpetic neuralgia, diabetic peripheral neuropathy, spinal cord injury, and seizures), the studies found prior authorization led to a shift toward use of other prescription medications, including prescription opioids (Margolis et al., 2009, 2010; Placzek et al., 2015).

Study Findings

This following section summarizes CHBRP's findings about the strength of evidence regarding the effects of step therapy and prior authorization on health outcomes and use of prescription medications and other health care services. 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.

Studies on the Impact of Step Therapy Protocols

Effects on Utilization of Initially Prescribed Medication

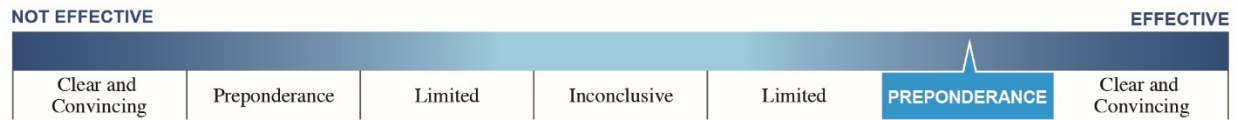
The AB 374 report found 12 studies of step therapy protocols that assessed their impact on use of prescription drugs subject to these protocols. These studies found that use of these drugs decreased after the step therapy protocols were implemented (Delate et al., 2005; Dunn et al., 2006; Farley et al., 2008; Hartung et al., 2004; Law et al., 2008; Mark et al., 2010; Smalley et al., 1995; Soumerai et al., 2008; Suehs et al., 2013; Udall et al., 2013; Yokoyama et al., 2007; Zhang et al., 2009). This finding is not surprising because step therapy protocols create financial incentives for enrollees to switch to the prescription medications preferred by their health plans.

A more recent study (Null et al., 2016) examined the impact of step therapy protocols on utilization of pregabalin (Lyrica®), an anticonvulsant medication, among patients with fibromyalgia, painful diabetic peripheral neuropathy, and postherpetic neuralgia. The study found the number of prescriptions for pregabalin had significantly increased among people enrolled in commercial plans before step therapy protocols were implemented, and there was a significant decrease in pregabalin prescriptions after these protocols were implemented.

Whether reduction in use of medications subject to step therapy protocols benefits or harms consumers depends on whether an equally effective medication with similar side effects is available and if consumers initiate prescriptions for these medications and take them as directed. In some cases, equally effective alternatives with similar side effects are available. If consumers take these medications as directed, health outcomes are unlikely to differ. On the other hand, if other medications used to treat a condition are less effective or have worse side effects, or if consumers do not take them as directed, step therapy protocols could have negative effects on health outcomes.

Summary of findings regarding the impact of step therapy protocols on utilization of initially prescribed medications: Preponderance of evidence suggests that step therapy protocols are associated with a decrease in use of initially prescribed medications. The consequences of reducing use of medications subject to step therapy protocols depends on whether consumers fill prescriptions for other equally effective medications and take them as directed.

Figure 3. Step Therapy Protocols on Utilization of Initially Prescribed Medications



Effects on Utilization of Other Prescription Medications

The literature review for AB 2144 identified four studies of the effects of step therapy protocols on use of other medications used to treat a disease or condition for which a medication is subject to a step therapy protocol (Kozma et al., 2015; Null et al., 2016; Suehs et al., 2015; Tang et al., 2017).

Guanfacine Extended-Release (GXR): Suehs et al. (2015) assessed the impact of coverage determinations (approval or denial) for children whose coverage for GXR, an FDA-approved medication for the treatment of ADHD that can be used alone or in addition to other stimulant treatments for ADHD, was subject to a step therapy protocol. The authors found that there were no statistically significant differences in use of other types of ADHD medications including amphetamine, methylphenidate, or atomoxetine, between children for whom a step therapy override was approved and those for whom the override was denied.

Pregabalin: Null et al. (2016) used an interrupted time series design to study the effects of step therapy protocols in commercial health plans on utilization of therapeutic alternatives to pregabalin (Lyrica®) that patients use for treatment of fibromyalgia; neuropathic pain due to postherpetic neuralgia, diabetic peripheral neuropathy, spinal cord injury, and partial onset seizures. This study found that after a step therapy protocol was implemented for pregabalin, there were statistically significant increases in the number of prescriptions for other anticonvulsants, opioids, serotonin and norepinephrine reuptake inhibitors (SNRIs), and selective serotonin reuptake inhibitors (SSRIs).

Sitagliptin (Januvia®): One study (Tang et al., 2017) compared claims for type 2 diabetes patients' use of dipeptidyl peptidase 4 (DPP-4) inhibitors, a class of medicines that lower high blood glucose levels, in three health plans that were similar prior to the implementation of step therapy for sitagliptin (Januvia®) by one of the health plans. Plan A implemented a step therapy protocol and placed sitagliptin in the third tier, Plan B placed sitagliptin in the third tier and did not implement a step therapy protocol, and C placed sitagliptin in the second tier and did not implement a step therapy protocol. Plan A required that patients who had not previously received DPP-4 inhibitor therapy use a preferred DPP-4 inhibitor, and required current users of sitagliptin to switch to one of the preferred DPP-4 inhibitors. Approximately 30% of patients in Plan A switched to another diabetes medication compared with approximately 15% and 2% of patients in Plans B and C, respectively. Seventeen percent of patients in Plan A discontinued sitagliptin without replacement but continued using other antidiabetes medications compared with approximately 13% and 8% of patients in Plans B and C, respectively.

Biologic medications: One study (Kozma et al., 2015) examined the percentage of patients with claims for infusion and subcutaneous biologic medications used to treat multiple diseases/conditions, including autoimmune disorders such as rheumatoid arthritis (RA) and inflammatory bowel disease (IBD). The infusion products were abatacept, infliximab, rituximab, and tocilizumab. The subcutaneous products

were dalimumab, anakinra, certolizumab pegol, etanercept, and golimumab. The study analyzed three different cohorts of patients in different health insurance plans. One cohort consisted of patients in health plans that imposed a step therapy requirement versus all others in the database (population), the second consisted of patients in step therapy plans versus patients who were members of plans whose characteristics were similar to those of the step therapy plans (matched), but did not require step therapy, and the third was a pre-post subsample of patients that were members of health plans that implemented step therapy. This study (Kozma et al., 2015) found 5.1% fewer patients with claims for infusion biologics among step therapy plans than among the overall plans (25.9% vs. 31.0%). However, in the matched step therapy study arm, infusion biologic use was higher in the step therapy plans than matched plans (25.9% vs. 18.9%). Additionally, in the pre-post arm of the study, there were more patients with infusion claims after step therapy protocols were implemented (12.4% and 15.2), but this difference was not statistically significant (Kozma et al., 2015).

Summary of findings regarding the impact of step therapy protocols on the utilization of other prescription drugs: Evidence is inconclusive that step therapy protocols increase or decrease the utilization of other prescriptions based on four studies. One study found that a step therapy protocol for pregabalin was associated with an increase in utilization of other prescription drugs used to treat fibromyalgia, neuropathic pain due to postherpetic neuralgia, diabetic peripheral neuropathy (pDPN), spinal cord injury, and partial onset seizures. Another study found that enrollees with diabetes who were subject to step therapy for sitagliptin were more likely to switch to other diabetes medications. By contrast, a study of step therapy for GXR for attention deficit hyperactivity disorder (ADHD) found no statistically significant difference in the use of other types of medications prescribed for ADHD. Another study found the findings regarding the impact of step therapy protocols on use of infusion biologics vary depending on the comparison group.

Figure 4. Step Therapy Protocols on Utilization of Other Prescription Medications



Effects on Initiation, Continuation, and Adherence to Prescription Medication

The AB 374 report identified seven studies of the impact of step therapy protocols on initiation, continuation, and adherence to prescription medications (Cox et al., 2004; Lu et al., 2010; Mark et al., 2009; Motheral et al., 2004; Soumerai et al., 2008; Yokoyama et al., 2007; Zhang et al., 2009). The literature review for AB 2144 identified three additional studies on this topic (Boytssov et al., 2020; Suehs et al., 2015; Tang et al., 2017).

Antipsychotic drugs: The strongest evidence of the impact of step therapy protocols on initiation, continuation, and adherence to medication comes from studies that examine the effects of a step therapy protocol implemented by Maine’s Medicaid program that use an interrupted time series with comparison group design. In 2003, Maine implemented a step therapy protocol for antipsychotic drugs. Enrollees with bipolar disorder who had not been prescribed an antipsychotic drug previously could not receive coverage for aripiprazole (Abilify®) or olanzapine (Zyprexa®) unless they had previously tried and failed treatment with risperidone (Risperdal®) and either quetiapine (Seroquel®) or ziprasidone (Geodon®).²⁷

²⁷ Persons previously prescribed Abilify or Zyprexa were grandfathered in (i.e., not subject to the step therapy protocol).

The authors reported that there was a 32% decrease in starting any antipsychotic drug among persons with bipolar disorder 4 months after the step therapy protocol was instituted (Lu et al., 2010).

Two studies examined the impact of the step therapy protocol implemented by Maine's Medicaid program on discontinuation of antipsychotic drugs (Soumerai et al., 2008; Zhang et al., 2009). Zhang and colleagues reported that following the implementation of the step therapy protocol, Maine Medicaid enrollees with bipolar disorder were 2.28 times more likely to discontinue antipsychotic drugs after 30 or more days of treatment than their counterparts in New Hampshire, who were not subject to step therapy. Similar effects were found for discontinuation after 50 or more days or 250 or more days of treatment. Soumerai and colleagues (2008) investigated the effect of the step therapy protocol on gaps, switching, or augmentation of drugs for Medicaid enrollees with schizophrenia. They found that Maine enrollees with schizophrenia were 1.94 times more likely to experience one of these circumstances.

Although these studies did not directly investigate effects of step therapy on health outcomes, it is plausible that lower rates of initiation and continuation of drugs or gaps in use of antipsychotic drugs could have adversely affected the mental health of persons with bipolar disorder or schizophrenia because discontinuing drugs for these conditions may exacerbate symptoms.

Antihypertensive drugs: Mark and colleagues (2009) evaluated step therapy protocols for antihypertensive drugs. They examined step therapy protocols that required employees and dependents with hypertension who received coverage through the employers to use certain (first-line or preferred) angiotensin-converting enzyme inhibitors (ACE inhibitors) or angiotensin receptor blocker (ARB) for a specified period of time before using another (second-line) ACE inhibitor or ARB. The authors found that following implementation of the step therapy protocols, the rate of discontinuation of antihypertensive drugs was larger in the step therapy group than in the comparison group. Discontinuing antihypertensive drugs may lead to adverse outcomes unless a person can control his or her blood pressure through diet and exercise alone. If not treated, hypertension increases a person's risk of having a stroke or developing heart disease.

Two studies on the impact of step therapy protocols on the number of days' supply of antihypertensive drugs reached opposite conclusions. One study found that step therapy was associated with a small and statistically significant difference in the number of days' supply of antihypertensive drugs (Yokoyama et al., 2007), whereas the other found no difference between persons who were and were not subject to a step therapy protocol (Mark et al., 2009).

Multiple Medications: CHBRP reviewed two studies that analyzed responses to surveys distributed to enrollees whose physicians prescribed antidepressants, NSAIDs, or protein pump inhibitors (PPIs) that were subject to step therapy protocols. The quality of these studies is low; the response rates were 23% and 33%, respectively, and sample sizes were small. Motheral and colleagues (2004) reported that 23% of enrollees who were prescribed a drug subject to a step therapy protocol obtained coverage for the initially prescribed medication and that 29% received a different drug covered by their health plan. Sixteen percent paid out of pocket for the initially prescribed medication. Five percent used an over-the-counter drug in the same therapeutic class. Overall, 17% did not obtain any drug. Cox and colleagues (2004) reported that 10% of enrollees subject to a step therapy protocol for NSAIDs and 13% of enrollees subject to a step therapy protocol for PPIs did not obtain any drug. The implications of Motheral and colleagues' and Cox and colleagues' studies are limited, because NSAIDs and PPIs are used for a wide range of conditions, some of which can be treated effectively without drugs or with over-the-counter drugs.

DMARDs: Boytsov et al. (2020) examined the impact of step therapy protocols on adherence to biologic DMARDs. This study defined medication adherence as filling prescriptions for an index DMARD for ≥80% of days during a 12-month period. The authors found that the odds of medication adherence was 19% lower among rheumatoid arthritis patients and 29% lower among psoriatic arthritis patients in health plans with step therapy protocols than among patients in plans without step therapy protocols. Lower adherence to medications used to treat rheumatoid arthritis and psoriatic arthritis could adversely affect

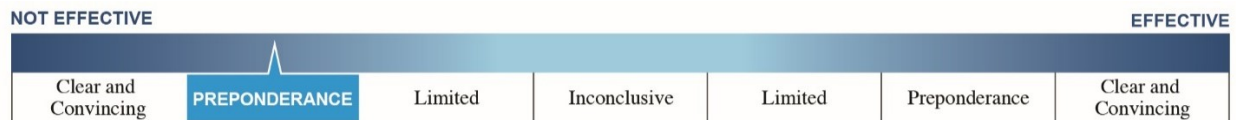
health outcomes because people with these conditions who do not take their medications as directed have a greater likelihood of disease progression, joint damage, and disability.

ADHD Medication: One study (Suehs et al., 2015) evaluated claims data for patients who received a step therapy coverage determination for GXR. The study authors found that enrollees for whom coverage for GXR was denied were more likely to receive no treatment for ADHD, had a greater number of treatment gap days, had a greater mean number of days between coverage denial and first ADHD medication claim, and a lower mean proportion of days covered with any ADHD medication than enrollees for whom coverage of GXR was approved. Only 50% of enrollees who were denied coverage for GXR received any alpha agonist treatment (primarily guanfacine immediate release, a short-acting version) during the follow-up period compared to 90% of those in the group for whom coverage of GXR was approved. (P < 0.001). The consequences of not adhering to medication for ADHD are not clear. Some people with ADHD can be treated successfully with behavioral therapy alone but others may need medication to manage their condition (NICE, 2019).

Diabetes Medication: Sitagliptin: One study (Tang et al., 2017) compared claims data for type 2 diabetes patients' use of antidiabetes medication in three different health plans, which were similar prior to the implementation of step therapy. Plan A implemented a step therapy protocol and placed sitagliptin (Januvia®) in the third tier, Plan B placed sitagliptin in the third tier and did not implement a step therapy protocol, and Plan C placed sitagliptin in the second tier and did not implement a step therapy protocol. Plan A required patients who had not previously received DPP-4 inhibitor therapy to use a preferred DPP-4 inhibitor, and required current users of sitagliptin to switch to one of the preferred DPP-4 inhibitors. After the step therapy protocol was implemented, 17% of patients in Plans A and B and 11% of patients in Plan C discontinued using all antidiabetes medications. This study did not examine the effects of step therapy on health outcomes but discontinuing all antidiabetes medications may adversely affect the health of people with type 2 diabetes because many of them cannot control their condition without medication.

Summary of findings regarding the impact of step therapy protocols on initiation, continuation, and supply of prescription medications: CHBRP found that the preponderance of evidence indicates that step therapy is associated with a lower likelihood of initiating or continuing medications and with poorer adherence to medication, based on eight studies of step therapy protocols for antipsychotic medications, antihypertensive medications, DMARDs, guanfacine extended-release, and sitagliptin. Poorer medication adherence may negatively affect health outcomes for all of these conditions because many people cannot manage them effectively without medication. Effects of step therapy on adherence to medications for other conditions are unknown.

Figure 5. Step Therapy Protocols on Initiation, Continuation, and Adherence to Prescription Medications



Effects on Treatment Effectiveness

Boytssov et al. (2020) assessed the impact of step therapy and prior authorization for DMARDs on the effectiveness of treatment for people with rheumatoid arthritis or psoriatic arthritis. The authors used a composite measure of treatment effectiveness. The DMARD a patient received at the start of the study period (i.e., the index medication) was deemed effective if the following six criteria were met; if the patient: (1) filled prescriptions for the medication for ≥80% of the time over a 12-month follow-up period; (2) did not switch to a new biologic DMARD or targeted synthetic DMARD; (3) did not have a new

conventional synthetic DMARD added to their medication regimen; (4) did not have an increase in dose or frequency of their index medication; (5) had fewer than two intra-articular glucocorticoid medications after the third month of the follow-up period; and (6) had no more than 30 days of an oral glucocorticoid after the third month of the follow-up period or an increase of 120% or less in the dose of a prescription for an oral glucocorticoid. They concluded that people with rheumatoid arthritis or psoriatic arthritis enrolled in health plans that required step therapy (with or without prior authorization) had lower odds of treatment effectiveness than people with these conditions who were enrolled in plans that did not require step therapy.

Summary of findings regarding the impact of step therapy protocols on treatment effectiveness: There is insufficient evidence to determine whether step therapy protocols affect treatment effectiveness because CHBRP found only one study regarding the effects of such protocols on treatment effectiveness. *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.

Figure 6. Step Therapy Protocols on Treatment Effectiveness

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

Effects on Health Outcomes

CHBRP identified only one study on the direct impact of step therapy protocols on health outcomes. Momani and colleagues (2002) evaluated the impact of a step therapy protocol for NSAIDs implemented by West Virginia’s Medicaid program on health-related quality of life among persons with chronic pain. Under this protocol, patients could not obtain coverage for a prescription for a brand-name NSAID unless they had tried at least two classes of generic NSAIDs for at least two weeks and failed to attain desired outcomes. Surveys were distributed to Medicaid enrollees under age 65 years who had osteoarthritis, rheumatoid arthritis, spondylitis, or chronic pain syndromes. Responses from persons who received prescriptions for generic NSAIDs were compared to persons who received prescriptions for brand-name NSAIDs. The study found no differences between the two groups in any of the domains of health-related quality of life measured, including mobility, walking and bending, hand and finger functioning, tension, and ability to perform self-care and engage in household and social activities.

Summary of findings regarding the impact of step therapy protocols on health outcomes: There is insufficient evidence to determine whether step therapy protocols directly affect health outcomes because CHBRP found only one study regarding the effects of such protocols on health outcomes among people with conditions that can cause chronic pain. *Insufficient evidence* indicates that there is not enough evidence available to know whether step therapy protocols affect health outcomes, 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.

Figure 7. Step Therapy Protocols on Health Outcomes



Effects of Step Therapy Protocols on Utilization of Other Medical Care

Eight studies included in CHBRP’s report on AB 374 evaluated the effects of step therapy protocols on use of medical services other than drugs. Five of these studies assessed the impact of utilization of medical services for conditions related to the prescription medication that was subject to a step therapy protocol (Delate et al., 2005; Farley et al., 2008; Mark et al., 2010; Suehs et al., 2013; Udall et al., 2013). Of these five studies, four were retrospective in study design, whereas one study (Delate et al., 2005) implemented an interrupted time-series analyses. Findings from these studies are inconclusive. Udall and colleagues (2013) and Suehs and colleagues (2013) reported on the effects of a step therapy protocol for anticonvulsant medication on outpatient visits among members of a commercial health plan. Among the plan’s commercial population aged 18 to 65 years, the step therapy protocol for anticonvulsant medication was associated with an increase in outpatient visits (Udall et al., 2013), whereas among the plan’s Medicare Advantage Prescription Drug members, the step therapy protocol for anticonvulsant found had no effect on outpatient visits (Suehs et al., 2013). Mark and colleagues (2010) reported that a step therapy protocol for antidepressants was associated with greater numbers of office visits, emergency department (ED) visits, and hospitalizations for mental health conditions. Farley and colleagues (2008) found that a step therapy protocol for antipsychotic medications implemented by Georgia’s Medicaid program was associated with a decrease in outpatient visits.²⁸ Delate and colleagues (2005) found that a Medicaid program’s step therapy protocol for proton pump inhibitors had no effect on expenditures for office visits, ED visits, and hospitalizations for gastrointestinal conditions.

Five studies assessed the impact of step therapy protocols on use of medical services for any medical condition. A study of a step therapy protocol for antihypertensive drugs reported that the step therapy protocol was associated with increases in office visits, ED visits, and hospitalizations for all causes (Mark et al., 2009). Two studies of the impact of step therapy protocols for NSAIDs on all-cause expenditures for office visits, ED visits, and hospitalizations reached the opposite conclusion. Hartung and colleagues (2004) found an increase in expenditures for ED visits, and Smalley and colleagues (1995) found no difference in utilization of office visits, ED visits, and hospitalizations. Two studies of a step therapy protocol for anticonvulsant medication reported that the step therapy protocol was associated with an increase in physical therapy visits (Suehs et al., 2013; Udall et al., 2013).

Summary of findings regarding effects of step therapy protocols on utilization of other medical care: The evidence regarding the impact of step therapy protocols on rates of hospital admissions, emergency department visits, and outpatient visits is inconclusive based on 8 studies included in CHBRP’s report on AB 374.

Figure 8. Step Therapy Protocols on Utilization of Other Medical Care



²⁸ Farley et al., 2008, found that expenditures for outpatient visits increased despite the decrease in the number of outpatient visits and suggested that providers may have been reimbursed more per visit.

Studies on the Impact of Prior Authorization

Effects on Use of Prescription Medications Subject to Prior Authorization

Prescription Opioids: From a literature review on state opioid misuse prevention policies, Mauri et al. (2020) identified three studies that found that prior authorization policies can reduce opioid prescribing. Hartung et al. (2018) found a Medicaid prior authorization policy in Oregon decreased high-dose opioid prescriptions and increased the use of low-dose opioid prescriptions following the policy implementation. Keast et al. (2018) found a Medicaid prior authorization policy in Oklahoma requiring a trial of short-acting opioids prior to initiating extended-release/long-acting therapy opioids created a decrease in new extended-release/long-acting opioid use among new opioid patients and increased short-acting opioid use. Morden et al. (2008) used Medicaid prescription claims to compare states whose Medicaid programs had strict, lenient, or no prior authorization for controlled-release oxycodone. The researchers found strict prior authorization was associated with a 34% reduction in controlled-release oxycodone use and lenient prior authorization was associated with a nonsignificant increase of 6%. An additional study (Barnett et al., 2018) evaluated the effect of a newly implemented prior authorization policy on extended release oxycodone. This policy was implemented by Blue Shield of California and affected people enrolled in its commercial health insurance plans. This study found prior authorization led to a 36% decrease in new prescriptions and an 11% decrease in total monthly prescriptions for extended-release oxycodone relative to people enrolled in commercial health plans that did not require prior authorization for extended-release oxycodone. However, at the same time, there was a 1.4% increase in short-acting opioid prescription fills, which indicates that there was no statistically significant overall change in the number of opioid prescriptions when prior authorization was implemented.

Buprenorphine: One study assessed the impact of prior authorization access to buprenorphine, a medication used to treat opioid use disorder. Andrews et al. (2019) used survey data from the National Drug Abuse Treatment System Survey to assess the relationship between utilization restrictions, including prior authorization, on buprenorphine availability at addiction treatment programs. The authors concluded that addiction treatment programs in states in which Medicaid required prior authorization had lower odds of offering buprenorphine.

Summary of findings on the effects of prior authorization on use of medications subject to prior authorization: There is limited evidence from four studies of prescription opioids and one study of buprenorphine that prior authorization reduces use of prescription medications subject to prior authorization. The implications of these findings differ for prescription opioids and buprenorphine. In the case of prescription opioids, short-acting opioids were substituted for long-acting opioids, yielding no statistically significant change in use of prescription opioids. In the case of buprenorphine, the finding of reduced availability is problematic because it is an effective treatment for opioid use disorder.

Figure 9. Effects of Prior Authorization on Use of Medications Subject to Prior Authorization



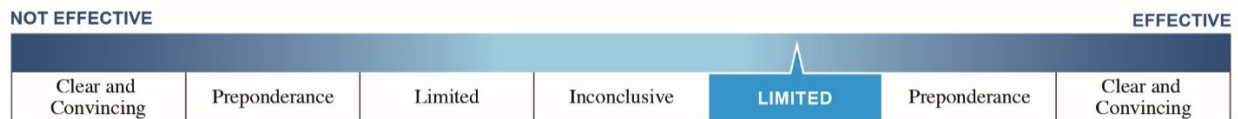
Effects of Prior Authorization on Use of Other Prescription Medications

A systematic review (Stacey et al. [2017]; three studies) examined the effectiveness of prior authorization policies for pregabalin (Lyrica®), a treatment approved for fibromyalgia, neuropathic pain due to

postherpetic neuralgia, diabetic peripheral neuropathy, spinal cord injury, and seizures. The studies found prior authorization led to a shift toward use of other prescription medications, including prescription opioids (Margolis et al., 2009, 2010; Placzek et al., 2015). Using Medicaid claims data, Margolis et al. (2009) found that patients with diabetic peripheral neuropathy or postherpetic neuralgia in states with prior authorization policies (two states, n = 424) had a smaller increase in pregabalin use (+9.2%) versus states without prior authorization policies (+13.6%; four states; n = 5,153). However, the states with prior authorization policies also had significantly more opioid claims than the unrestricted states (6.5%). Additionally, there were significantly more claims for other nonopioid analgesics, “other antidepressants” (i.e., bupropion, citalopram, duloxetine, paroxetine, trazodone, venlafaxine), and anxiolytics in states with prior authorization versus unrestricted states. Margolis et al. (2010) found that commercial health plans with prior authorization policies reduced pregabalin utilization compared to commercial health plans without prior authorization policies (+7.5 vs +12.8 percentage points). Commercial health plans with prior authorization plans had significantly more claims for other antiepileptic drugs (+ 3.7%) and nonopioid analgesic medications (+5.2%). Additionally, in a retrospective cohort study of commercially insured patients, Placzek et al. (2015) found opioid usage was significantly higher among persons with fibromyalgia who were enrolled in a health plan that required prior authorization for pregabalin. The implications of substituting other medications for pregabalin depend on the other medication used. In the case of anticonvulsant medications, the impact may be minimal if other anticonvulsants have similar risks and benefits. On the other hand, substituting prescription opioids for pregabalin could harm patients because people who take prescription opioids have a greater risk of misuse and overdose.

Summary of findings on the effects of prior authorization on use of other prescription medications: There is limited evidence of the effects of prior authorization on use of medications not subject to prior authorization. Findings from three studies found that prior authorization for pregabalin was associated with an increase in prescriptions for other medications. Some of these prescriptions were for other anticonvulsant medications which may have similar risks and benefits, whereas others were for opioids, which have greater risks of misuse and overdose.

Figure 10. Effects of Prior Authorization on Use of Other Prescription Medications



Effects of Prior Authorization on Health Outcomes

One study examined the impact of prior authorization on rates of opioid medication abuse and overdoses. The study examined a cohort of Medicaid enrollees who initiated a new opioid medication not used for addiction treatment. Cochran et al. (2017) compared plans with no prior authorization (six plans) to a low prior authorization plan (one plan) which required prior authorization for one prescription opioid medication on the formulary to high prior authorization plans (two plans), which required prior authorization for many opioids on the formulary (17 and 74 prescription opioid medications on the formulary). The study found that compared to people enrolled in plans with no prior authorization, enrollees in both high prior authorization and low prior authorization plans had significantly lower rates of opioid abuse. Enrollees in the low prior authorization plan had significantly lower rates of overdose than enrollees in plans with no prior authorization. People enrolled in the high prior authorization plans also were less likely to overdose, but the difference was not statistically significant.

Summary of findings on the effects of prior authorization on health outcomes: CHBRP concludes that the evidence on the direct effect of prior authorization on health outcomes is insufficient because CHBRP found only one study of prior authorization for one class of medications. *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.

Figure 11. Effects of Prior Authorization on Health Outcomes

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

Summary of Findings

Impact of Step Therapy Protocols

- *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 and 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 medication is essential for effective treatment of the condition.
- CHBRP concludes that 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.
- CHBRP concludes that 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.
- Findings from studies of the impact of step therapy protocols on utilization of other types of medical services are *inconclusive*.

Impact of Prior Authorization

- CHBRP concludes that there is *limited evidence* that prior authorization policies 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.
- CHBRP concludes that there is *limited evidence* that prior authorization policies increase use of other prescription medications. Whether an 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.

- CHBRP concludes that the evidence on the effect of prior authorization on health outcomes is *insufficient* because we found only one study of prior authorization for one class of medications.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, AB 2144 would require DMHC-regulated health plans and CDI-regulated policies with commercial and CalPERS enrollees²⁹ that include both an outpatient medication benefit and step therapy or prior authorization protocols to grant or deny decisions within specified timeframes; that requests for step therapy overrides be granted under five particular identified circumstances that may occur; provide for streamlined appeals procedures for prior authorization or step therapy override denials; and impose reporting and appeal panel requirements.

CHBRP assessed benefit coverage, utilization, and cost impacts of AB 2144 on the health insurance of commercial/CalPERS enrollees. AB 2144 would not require coverage of medications not on the plan/policy formulary or prohibit utilization management protocols, or prohibit cost sharing. CHBRP assumed that the total number of prescriptions written and filled will remain constant, pre- and postmandate.³⁰ The literature suggests that utilization management protocols might affect overall prescribing, but AB 2144 does not eliminate step therapy or prior authorization where they already exist. AB 2144 only allows for the more expedient decisions on step therapy override and prior authorization requests. This will shift utilization from alternative or required medications to the initially prescribed medication rather than increasing the total number of prescriptions. As an approach for this report, CHBRP focuses the analysis on step therapy that discourage use of the more expensive medications before trying the less expensive alternative (see the *Background* section for greater detail). CHBRP assumes that where step therapy exists, an override would move a patient from the, on average, less expensive step therapy–required medication in the same medication class to the generally more expensive initially prescribed medication.

This section reports the potential incremental impacts of AB 2144 on estimated baseline benefit coverage, utilization, and overall cost. For further details on the underlying data sources and methods used in this analysis, please see Appendix C.

Baseline and Postmandate Benefit Coverage

Almost all — over 92% — commercial/CalPERS enrollees have a pharmacy benefit regulated by DMHC or CDI that covers both generic and brand-name outpatient prescription medications.³¹ Because AB 2144 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. Approximately 0.2% of commercial enrollees have a generic-only pharmacy benefit. Because AB 2144 does not require coverage of higher tier medications, these plans are considered compliant with AB 2144.

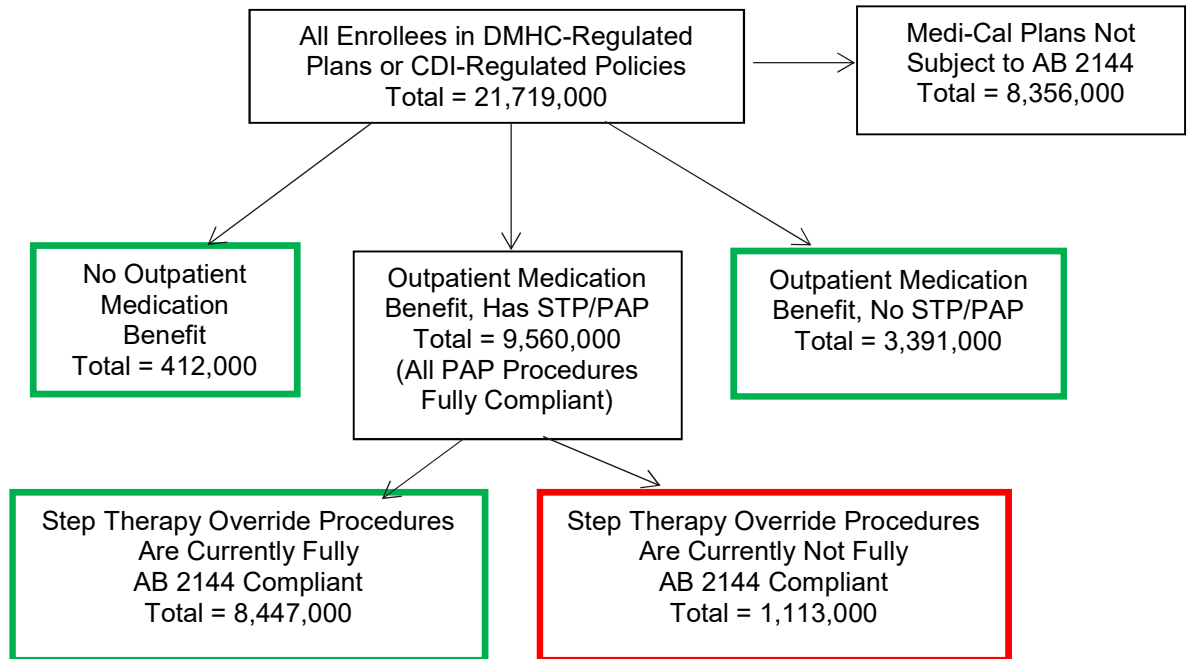
The following types of benefit coverage are fully compliant with AB 2144: 1) no outpatient medication benefit; 2) an outpatient medication benefit that has no step therapy/prior authorization; and 3) an outpatient medication benefit that has step therapy and/or prior authorization, and has override procedures that fully comply with AB 2144 (see Table 1). CHBRP estimates that 91.7% of commercial/CalPERS enrollees (9,972,000) currently have coverage that is fully compliant with AB 2144, and 8.3% (1,113,000) have coverage that includes step therapy override procedures that are not fully compliant with AB 2144 (see Table 1, as well as Figure 10 and Table 4, both below). All plans and insurers responding to the Carrier Survey indicated that existing prior authorization protocols are fully compliant with AB 2144.

²⁹ AB 2144 exempts from compliance DMHC-regulated plans enrolling Medi-Cal beneficiaries.

³⁰ Personal communication with content expert D. Stern on March 11, 2020.

³¹ For more detail, see *Estimates of Pharmacy Benefit Coverage in California for 2021*, available at http://chbrp.org/other_publications/index.php.

Figure 12. Baseline of Enrollee Benefit Coverage and Status of Mandate Compliance Under AB 2144



Note: Numbers may not add to totals due to rounding.

Key: CDI = California Department of Insurance; DMHC = Department of Managed Health Care; PAP = prior authorization protocol; STP = step therapy protocol.

Current step therapy, prior authorization protocols, and override requests were determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represent 67% of enrollees with commercial or CalPERS health insurance that can be subject to state mandates.

Although CHBRP found that all commercial/CalPERS enrollees with outpatient medication benefits that include step therapy or prior authorization protocols have override procedures, not all were compliant with all of the step therapy override criteria specified by AB 2144. CHBRP estimates that 11.6% (see Figure 3) of commercial/CalPERS enrollees in plans with step therapy and prior authorization protocols have coverage that is currently not compliant with all of AB 2144’s step therapy-related requirements, though these plans are compliant with many of the requirements. All plans seem to be compliant with prior authorization protocol requirements and with the requirement of the use of clinical peer evaluation of appeals, so no change is projected due to these requirements. All other enrollees are enrolled in plans that are fully compliant with AB 2144.

This baseline assumes that any use of step therapy or prior authorization would fall under AB 2144, regardless of the number of medications subject to the protocols for that particular DMHC-regulated plan or CDI-regulated policy. However, it must be noted that not all step therapy or prior authorization protocols include the same number of medication classes or medications, with a range of 62 to 280 medications subject to step therapy, and 125 to 992 medications subject to prior authorization within an outpatient prescription medication benefit included in a plan or policy (see Table 2). CHBRP assumes that

enrollees in these DMHC-regulated plans and CDI-regulated policies are equally able to request an override.

Table 2. Number of Medications Subject to Step Therapy Protocols by Percent of Commercial/CalPERS Enrollees

OPM Benefit	% of All Enrollees*
Enrollees with no OPM	3.1
Enrollees with OPM—unknown number of medications subject to step therapy	26.1
Enrollees with OPM—no medication subject to step therapy	51.6
Enrollees with OPM—1 medication subject to step therapy	0.0
Enrollees with OPM—2–100 medications subject to step therapy	2.8
Enrollees with OPM—more than 100 medications subject to step therapy	16.4
Total enrollees in all DMHC-regulated plans or CDI-regulated policies	100%

Source: California Health Benefits Review Program, 2020.

Note: * Commercial/CalPERS enrollees subject to step therapy.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; OPM = outpatient prescription medication.

Table 3. Number of Medications Subject to Prior Authorization Protocols by Percent of Commercial/CalPERS Enrollees

OPM Benefit	% of All Enrollees*
Enrollees with no OPM	3.1
Enrollees with OPM—unknown number of medications subject to prior authorization	26.1
Enrollees with OPM—no medication subject to prior authorization	51.6
Enrollees with OPM—1 medication subject to prior authorization	0.0
Enrollees with OPM—2–200 medications subject to step therapy	2.4%
Enrollees with OPM—more than 200 medications subject to step therapy	16.8
Total enrollees in all DMHC-regulated plans or CDI-regulated policies	100%

Source: California Health Benefits Review Program, 2020.

Note: * Commercial/CalPERS enrollees subject to step therapy.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; OPM = outpatient prescription medication.

Table 4. Commercial/CalPERS Enrollees With Currently AB 2144–Compliant Benefit Coverage

AB 2144 Step Therapy and Prior Authorization Requirements	% of Commercial/CalPERS Enrollees*
Prior authorization decisions provided within 72 hours (nonurgent)/24 hours (urgent)	100%
Step therapy decisions provided within 72 hours (nonurgent)/24 hours (urgent)	100%
New Enrollees exempted from step therapy requirements previously completed	96.1%
Step therapy exemption if step therapy–required medication indicated by the protocol is contraindicated or likely to cause an adverse reaction (mental or physical harm) in the patient	100%
Step therapy exemption if step therapy–required medication is expected to be ineffective due to the patient’s mental or physical characteristics.	100%
Step therapy exemption if step therapy–required medication is not medically appropriate	100%
Step therapy exemption if step therapy–required medication is not FDA approved as a treatment for the patient’s condition	100%
Step therapy exemption if the patient is stable on the initially prescribed medication	96.6%

Source: California Health Benefits Review Program, 2020.

Note: * Current % of commercial/CalPERS enrollees with coverage that includes step therapy overrides and prior authorization granted for AB 2144 criteria.

Key: CalPERS = California Public Employees’ Retirement System; FDA = Food and Drug Administration.

Baseline and Postmandate Utilization

At baseline, CHBRP estimates that 62,806 step therapy overrides and 1,493,526 prior authorizations were granted to commercial/CalPERS enrollees. These number are estimates based on the responses to the Carrier Survey applied over the entire insured population.

Postmandate, CHBRP estimates that the number of step therapy overrides granted to commercial/CalPERS enrollees will increase to 63,351 (see Table 1) for an increase of 544 step therapy overrides, annually. CHBRP estimates that the override requests granted postmandate will increase by 0.87% because enrollees with new mandate-compliant coverage will increase their use of step therapy override procedures to match the same rate as enrollees who already had mandate-compliant coverage during the premandate period. CHBRP does not project a change in prior authorizations because carriers appear to be fully consistent with the prior authorization requirements of AB 2144.

Baseline and Postmandate Per-Unit Cost

CHBRP estimates that the premandate and postmandate average per-unit cost of the initially prescribed medication when a step therapy override or prior authorization is granted will remain the same, because there will be no measureable change in the overall utilization of any specific medication. Utilization is expected to shift toward more expensive drugs, however, so that the average unit cost of dispensed medications will increase. The impacts of AB 2144 are not expected be materially different in subsequent years.

Baseline and Postmandate Expenditures

Table 5 and Table 6 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).

AB 2144 would increase total net annual expenditures by \$721,000 or less than 0.01% for commercial/CalPERS enrollees. This is due to a \$456,000 increase in employer premiums, a \$137,000 increase in the employee share of group premiums, a \$3,000 increase in individual premiums, and a \$125,000 increase in enrollee out-of-pocket expenditures.

Premiums

Changes in premiums as a result of AB 2144 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 5, and Table 6), with health insurance that would be subject to AB 2144.

CHBRP estimates that the largest premium impact of AB 2144 will be in the CDI-regulated small-group and large-group market segment, each of which will see a \$0.06 increase in average premiums. Premiums in other segments of the Commercial market are projected to increase \$0.01 or less.

Among CalPERS plans, there is not expected to be any impact from AB 2144, as all plan coverage of outpatient prescription medications is compliant with AB 2144. Medi-Cal Managed Care plans are exempted from AB 2144 requirements.

Enrollee Expenses

AB 2144–related changes in enrollee expenses for covered benefits (deductibles, copays, etc.) and enrollee expenses for noncovered benefits would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 5, and Table 6) with health insurance that would be subject to AB 2144 who would be expected to use additional prescriptions of the initially prescribed medication during the year after enactment.

CHBRP projects no change to copayments or coinsurance rates but does project an increase in utilization of initially prescribed medications, which are typically more expensive than alternative medications within the same therapeutic class, and therefore an increase in enrollee cost sharing.

Out-of-pocket spending for covered and noncovered expenses

CHBRP is unable to estimate the number of enrollees with uncovered expenses at baseline nor the reduction in their out-of-pocket expenses associated with outpatient medications subject to step therapy and preauthorization protocols for which they may pay for out of pocket in the baseline. Any reduction in expenses would result only from the projected 544 additional overrides (Table 1).

Potential cost offsets or savings in the first 12 months after enactment

CHBRP does not project any cost offsets or savings in health care that would result because of the enactment of provisions in AB 2144. It is possible that such savings could arise from a reduction in medical treatment required, as noted in the *Medical Effectiveness* section, the evidence for this possibility is inconclusive.

Postmandate administrative expenses and other expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies will 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.

Other Considerations for Policymakers

In addition to the impacts a bill may have on benefit coverage, utilization, and cost, other related considerations for policymakers are discussed below.

Postmandate Changes in the Number of Uninsured Persons

CHBRP estimates premium increases of less than 1% for each market segment; this premium increase would not have a measurable impact on the number of persons who are uninsured. CHBRP does not anticipate loss of health insurance, changes in availability of the benefit beyond those subject to the mandate, changes in offer rates of health insurance, changes in employer contribution rates, changes in take-up of health insurance by employees, or purchase of individual market policies, due to the small size of the increase in premiums after the mandate.

Because the change in average premiums does not exceed 1% for any market segment (see Table 1, Table 5, and Table 6), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 2144.

Changes in Public Program Enrollment

CHBRP estimates that there would be no measurable impact on enrollment in publicly funded insurance programs due to the enactment of AB 2144.

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

CHBRP estimates that there are no cost shifts to other payers due to premandate noncompliance with AB 2144 requirements for enrollees with DMHC-regulated plans or CDI-regulated policies. When granted, step therapy override requests may or may not increase costs for the patients, who face higher copayments or coinsurance for the initially prescribed medication. Therefore, CHBRP estimates no associated costs are shifted to other payers due to lack of mandate-compliant coverage.

Table 5. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2021

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) (a)			Publicly Funded Plans			Privately Funded Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS HMOs (b)	MCMC (Under 65) (c)	MCMC (65+) (c)	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	7,797,000	2,127,000	1,938,000	522,000	7,481,000	875,000	645,000	174,000	160,000	21,719,000
Total enrollees in plans/policies subject to AB 2144	7,797,000	2,127,000	1,938,000	522,000	0	0	645,000	174,000	160,000	13,363,000
Premiums										
Average portion of premium paid by employer	\$421.33	\$387.36	\$0.00	\$521.09	\$262.75	\$536.28	\$493.36	\$435.79	\$0.00	\$86,519,976,000
Average portion of premium paid by employee	\$109.79	\$140.13	\$632.59	\$97.10	\$0.00	\$0.00	\$137.09	\$167.01	\$509.49	\$31,556,986,000
Total premium	\$531.12	\$527.49	\$632.59	\$618.19	\$262.75	\$536.28	\$630.44	\$602.80	\$509.49	\$118,076,962,000
Enrollee expenses										
For covered benefits (deductibles, copays, etc.)	\$41.92	\$115.98	\$170.63	\$51.02	\$0.00	\$0.00	\$123.80	\$161.70	\$161.76	\$12,776,801,000
For noncovered benefits (e)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0
Total expenditures	\$573.05	\$643.47	\$803.22	\$669.20	\$262.75	\$536.28	\$754.24	\$764.50	\$671.25	\$130,853,763,000

Source: California Health Benefits Review Program, 2020.

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

(b) Approximately 57.36% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five (20.5%) of these enrollees has a pharmacy benefit not subject to DMHC. CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

(c) Medi-Cal Managed Care Plan expenditures for members over 65 years include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

Analysis of California Assembly Bill 2144

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

(e) 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 currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care.

Table 6. Postmandate Per Member Per Month Premiums and Total Expenditures Impacts by Market Segment, California, 2021

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) (a)			Publicly Funded Plans			Privately Funded Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS HMOs (b)	MCMC (Under 65) (c)	MCMC (65+) (c)	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	7,797,000	2,127,000	1,938,000	522,000	7,481,000	875,000	645,000	174,000	160,000	21,719,000
Total enrollees in plans/policies subject to AB 2144	7,797,000	2,127,000	1,938,000	522,000	0	0	645,000	174,000	160,000	13,363,000
Premiums										
Average portion of premium paid by employer	\$0.0001	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0463	\$0.0437	\$0.0000	\$456,000
Average portion of premium paid by employee	\$0.0000	\$0.0000	\$0.0001	\$0.0000	\$0.0000	\$0.0000	\$0.0129	\$0.0168	\$0.0000	\$140,000
Total premium	\$0.0001	\$0.0000	\$0.0001	\$0.0000	\$0.0000	\$0.0000	\$0.0592	\$0.0605	\$0.0000	\$596,000
Enrollee expenses										
For covered benefits (deductibles, copays, etc.)	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0116	\$0.0161	\$0.0000	\$125,000
For noncovered benefits (e)	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
Total expenditures	\$0.0001	\$0.0000	\$0.0002	\$0.0000	\$0.0000	\$0.0000	\$0.0708	\$0.0766	\$0.0000	\$721,000
Percent change										
Premiums	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0094%	0.0100%	0.0000%	0.0005%
Total expenditures	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0094%	0.0100%	0.0000%	0.0006%

Source: California Health Benefits Review Program, 2020.

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

Analysis of California Assembly Bill 2144

(b) Approximately 57.36% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five (20.5%) of these enrollees has a pharmacy benefit not subject to DMHC. CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

(c) Medi-Cal Managed Care Plan expenditures for members over 65 years include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

(e) 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 currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care.

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, for health plans and policies that have step therapy protocols in place for prescription medications, AB 2144 would define circumstances in which a step therapy override must be granted and would establish a deadline for approval or denial of requests for step therapy overrides and prior authorization. The insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans would be exempt from these requirements. 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 impact of AB 2144 on health outcomes. See the *Long-Term Impacts* section for discussion of social determinants of health.

Estimated Public Health Outcomes

Due to the variation of impact on benefit coverage, the public health impacts regarding AB 2144's requirements for step therapy protocols and prior authorization protocols also differ.

Prior Authorization

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, 100% of enrollees currently have coverage that requires prior authorization request responses within guidelines mandated under AB 2144. For these enrollees, the passage of AB 2144 would not result in a change in benefit coverage and so would cause no public health impacts.

Step Therapy

Although the particular lists vary among enrollees with different health plans and policies, a wide range of prescription medications can be associated with step therapy protocols. The range can include antipsychotic, antihypertensive, biologic disease-modifying antirheumatic, ADHD, and diabetes medications.

Measurable health outcomes relevant to AB 2144 are dependent on the type of medication subject to step therapy protocols. For some types of medications, such as antipsychotic and diabetes medications, a reduced rate of initiation and continuation of medication could have adverse impacts, such as exacerbated symptoms of psychological disorders or an inability to control a patient's diabetes condition. In other cases, such as proton pump inhibitors, some patients are able to manage their symptoms by taking over-the-counter medications and/or changing their diet.

However, as there is insufficient evidence to determine whether step therapy protocols directly impact health outcomes, the effect of AB 2144 on health outcomes for the estimated 544 enrollees for whom additional step therapy overrides would be approved is unknown.

In the first year postmandate, no public health impact is expected regarding prior authorization, because benefit coverage is already compliant. 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.

Impact on Disparities³²

CHBRP found no studies on the impact of step therapy protocols, step therapy override procedures, or the length of time for prior authorization on racial and ethnic disparities or SDoH.

Racial or Ethnic Disparities

The extent to which AB 2144 would have an impact on possible racial or ethnic disparities is unknown due to a lack of evidence on the effect of the use of step therapy protocols, override procedures, or prior authorization on racial and ethnic disparities.

³² 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.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of AB 2144, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

Utilization Impacts

In the 12 months following enactment, CHBRP estimates that utilization will increase from 3.842 step therapy overrides per 1,000 enrollees to 3.844 overrides per 1,000. No increase is projected in the baseline 71.13 prior authorizations granted per 1,000 enrollees. In later years, the rate is likely to remain the same, but the recent trend in the private market toward increasing the number of enrollees in both DMHC-regulated plans and CDI-regulated policies that have step therapy protocols in place (see the *Background* section) will likely continue.

Cost Impacts

As there is no literature that specifically focuses on the cost-effectiveness of step therapy overrides, CHBRP cannot estimate the long-term impact of this particular piece of step therapy protocols.

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 social determinants of health, premature death, and economic loss.

In the case of AB 2144, CHBRP estimates no change in utilization rate beyond 12 months postmandate; therefore, there are no estimated long-term impacts of step therapy protocols, step therapy overrides, or prior authorization on long-term public health outcomes.

Impacts on Disparities and the Social Determinants of Health³³

CHBRP found no studies on the impact of step therapy protocols, step therapy override procedures, or the length of time for prior authorization on racial and ethnic disparities or SDoH, and there are no estimated long-term impacts of the mandates of AB 2144.

CHBRP projects no changes in the racial and ethnic disparities or SDoH that would be attributed to AB 2144 for enrollees who have coverage subject to its mandates.

³³ For more information about SDoH, see CHBRP's publication Incorporating Relevant Social Determinants of Health Into CHBRP Benefit Mandate Analyses at http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

APPENDIX A TEXT OF BILL ANALYZED

On February 14, 2020, the California Assembly Committee on Health requested that CHBRP analyze AB 2144, which was introduced on February 10, 2020.

On February 26, 2020, the Assembly Health Committee asked CHBRP to analyze the language with proposed amendments. The version below includes those amendments.

ASSEMBLY BILL

NO. 2144

Introduced by Assembly Member Arambula

February 10, 2020

An act to amend Sections 1367.241 and 1367.244 of, and to add Section 1367.206 to, the Health and Safety Code, and to amend Sections 10123.191, 10123.197, and 10123.201 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 2144, as amended, Arambula. Health care coverage: step therapy.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene), 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 a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law authorizes a health insurer to require step therapy if there is more than one drug that is appropriate for the treatment of a medical condition, and authorizes a health care service plan to utilize step therapy consistent with Knox-Keene. Under existing law, if a health care service plan, health insurer, or contracted physician group fails to respond to a completed prior authorization request from a prescribing provider within a specified timeframe, the prior authorization request is deemed to have been granted.

This bill would clarify that a health care service plan may require step therapy if there is more than one drug that is appropriate for the treatment of a medical condition. The bill would require a health care service plan or health insurer to expeditiously grant a step therapy exception if specified criteria are met. The bill would authorize an enrollee or insured or their designee, guardian, primary care physician, or health care provider to file an appeal of a prior authorization or the denial of a step therapy exception request, and would require a health care service plan or health insurer to designate a clinical peer to review those appeals. The bill would require a health care service plan, health insurer, or utilization review organization to annually report specified information about their step therapy exception requests and prior authorization requests to the Department of Managed Health Care or the Department of Insurance, as appropriate. The bill

would require a prior authorization request or step therapy exception request to be deemed to have been granted if a health care service plan, health insurer, or contracted physician group fails to send an approval or denial within a specified timeframe. Because a willful violation of the bill's requirements relative to health care service plans 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.

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

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

SECTION 1. Section 1367.206 is added to the Health and Safety Code, to read:

1367.206. (a) If there is more than one drug that is appropriate for the treatment of a medical condition, a health care service plan may require step therapy.

(b) If an enrollee is changing contracts, the new contract shall not require an enrollee to repeat step therapy if that enrollee is already being treated for a medical condition by a prescription drug, provided that the drug is appropriately prescribed and is considered safe and effective for the enrollee's condition. This section does not preclude the new contract from imposing a prior authorization requirement for the continued coverage of a prescription drug prescribed pursuant to step therapy imposed by the former contract, or preclude the prescribing provider from prescribing another drug covered by the new contract that is medically appropriate for the insured.

(c) A step therapy exception shall be expeditiously granted if any of the following criteria are met:

(1) The required prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the enrollee.

(2) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the enrollee and the known characteristics of the prescription drug regimen.

(3) The enrollee has tried the required prescription drug, or another prescription drug in the same pharmacologic class or with the same mechanism of action, while covered by their current or previous health insurance policy or health benefit plan contract, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(4) The required prescription drug is not in the best interest of the enrollee, based on medical necessity.

(5) The enrollee is stable on a prescription drug selected by their health care provider for the medical condition under consideration while covered by their current or previous health care service plan contract or health insurance policy.

(d) An enrollee or the enrollee's designee, guardian, primary care physician, or health care provider may file an appeal of a prior authorization or the denial of a step therapy exception request. A health care service plan shall designate a clinical peer to review appeals, because these appeals pertain to medical or clinical matters and an appeal must be reviewed by an appropriate health care professional. A clinical peer reviewing an appeal shall not have had any involvement in the initial determination that is the subject of the appeal.

(e) This section does not prohibit either of the following:

(1) A health care service plan or utilization review organization from requiring an enrollee to try an AB-rated generic equivalent before providing coverage for the equivalent branded prescription drug.

(2) A health care provider from prescribing a prescription drug that is determined to be medically appropriate.

(f) The health care service plan or utilization review organization shall report the following information to the department annually, in a format prescribed by the department:

(1) The number of step therapy exception requests and prior authorization requests received.

(2) The type of health care providers or the medical specialties of the health care providers submitting requests.

(3) The number of step therapy exception requests that were initially denied and the reasons for the denials.

(4) The number of step therapy exception requests that were initially approved.

(5) The number of step therapy exception denials that were reversed by an internal appeal or an external review.

(g) This section does not apply to contracts entered into pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14591) of Part 3 of Division 9 of the Welfare and Institutions Code.

~~(g)~~

(h) For purposes of this section:

(1) “Clinical peer” means a health care professional who is in the same profession and the same or similar specialty as the health care provider who typically manages the medical condition, procedures, or treatment under review.

(2) “Step therapy exception” means a step therapy protocol that is overridden in favor of immediate coverage of the prescription drug prescribed by a health care provider.

SEC. 2. Section 1367.241 of the Health and Safety Code is amended to read:

1367.241. (a) Notwithstanding any other law, on and after January 1, 2013, a health care service plan that provides coverage for prescription drugs shall accept only the prior authorization form developed pursuant to subdivision (c), or an electronic prior authorization process described in subdivision (e), when requiring prior authorization for prescription drugs. This section does not apply in the event that a physician or physician group has been delegated the financial risk for prescription drugs by a health care service plan and does not use a prior authorization process. This section does not apply to a health care service plan, or to its affiliated providers, if the health care service plan owns and operates its pharmacies and does not use a prior authorization process for prescription drugs.

(b) If a health care service plan or a contracted physician group fails to send an approval or denial within 72 hours for nonurgent requests, and within 24 hours if exigent circumstances exist, upon receipt of a completed prior authorization request or step therapy exception request from a prescribing provider, the prior authorization request or step therapy exception request shall be deemed to have been granted. The requirements of this subdivision shall not apply to contracts entered into pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14591) of Part 3 of Division 9 of the Welfare and Institutions Code. Medi-Cal managed care health care service plans that contract under those chapters shall not be required to maintain an external exception request review as provided in Section 156.122 of Title 45 of the Code of Federal Regulations.

(c) On or before January 1, 2017, the department and the Department of Insurance shall jointly develop a uniform prior authorization form. Notwithstanding any other law, on and after July 1, 2017, or six months after the form is completed pursuant to this section, whichever is later, every prescribing provider shall use that uniform prior authorization form, or an electronic prior authorization process described in subdivision (e), to request prior authorization for coverage of prescription drugs and every health care service plan shall accept that form or electronic process as sufficient to request prior authorization for prescription drugs.

(d) The prior authorization form developed pursuant to subdivision (c) shall meet the following criteria:

(1) The form shall not exceed two pages.

(2) The form shall be made electronically available by the department and the health care service plan.

(3) The completed form may also be electronically submitted from the prescribing provider to the health care service plan.

(4) The department and the Department of Insurance shall develop the form with input from interested parties from at least one public meeting.

(5) The department and the Department of Insurance, in development of the standardized form, shall take into consideration the following:

(A) Existing prior authorization forms established by the federal Centers for Medicare and Medicaid Services and the State Department of Health Care Services.

(B) National standards pertaining to electronic prior authorization.

(e) A prescribing provider may use an electronic prior authorization system utilizing the standardized form described in subdivision (c) or an electronic process developed specifically for transmitting prior authorization information that meets the National Council for Prescription Drug Programs' SCRIPT standard for electronic prior authorization transactions.

(f) Subdivision (a) does not apply if any of the following occurs:

(1) A contracted physician group is delegated the financial risk for prescription drugs by a health care service plan.

(2) A contracted physician group uses its own internal prior authorization process rather than the health care service plan's prior authorization process for plan enrollees.

(3) A contracted physician group is delegated a utilization management function by the health care service plan concerning any prescription drug, regardless of the delegation of financial risk.

(g) For prescription drugs, prior authorization requirements described in subdivisions (c) and (e) apply regardless of how that benefit is classified under the terms of the health plan's group or individual contract.

(h) For purposes of this section:

(1) "Prescribing provider" shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an enrollee.

(2) "Exigent circumstances" exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a nonformulary drug.

(3) "Completed prior authorization request" means a completed uniform prior authorization form developed pursuant to subdivision (c), or a completed request submitted using an electronic prior authorization system described in subdivision (e), or, for contracted physician groups described in subdivision (f), the process used by the contracted physician group.

(4) “Step therapy exception” means a step therapy protocol that is overridden in favor of immediate coverage of the prescription drug prescribed by a health care provider.

SEC. 3. Section 1367.244 of the Health and Safety Code is amended to read:

1367.244. (a) A request for an exception to a health care service plan’s step therapy process for prescription drugs may be submitted in the same manner as a request for prior authorization for prescription drugs pursuant to Section 1367.241, and shall be treated in the same manner, and shall be responded to by the health care service plan in the same manner, as a request for prior authorization for prescription drugs.

(b) The department and the Department of Insurance shall include a provision for step therapy exception requests in the uniform prior authorization form developed pursuant to subdivision (c) of Section 1367.241.

(c) “Step therapy exception” means a step therapy protocol that is overridden in favor of immediate coverage of the prescription drug prescribed by a health care provider.

SEC. 4. Section 10123.191 of the Insurance Code is amended to read:

10123.191. (a) Notwithstanding any other law, on and after January 1, 2013, a health insurer that provides coverage for prescription drugs shall utilize and accept only the prior authorization form developed pursuant to subdivision (c), or an electronic prior authorization process described in subdivision (e), when requiring prior authorization for prescription drugs.

(b) If a health insurer or a contracted physician group fails to send an approval or denial within 72 hours for nonurgent requests, and within 24 hours if exigent circumstances exist, upon receipt of a completed prior authorization request or step therapy exception request from a prescribing provider, the prior authorization request or step therapy exception request shall be deemed to have been granted.

(c) On or before January 1, 2017, the department and the Department of Managed Health Care shall jointly develop a uniform prior authorization form. Notwithstanding any other law, on and after July 1, 2017, or six months after the form is completed pursuant to this section, whichever is later, every prescribing provider shall use that uniform prior authorization form, or an electronic prior authorization process described in subdivision (e), to request prior authorization for coverage of prescription drugs and every health insurer shall accept that form or electronic process as sufficient to request prior authorization for prescription drugs.

(d) The prior authorization form developed pursuant to subdivision (c) shall meet the following criteria:

(1) The form shall not exceed two pages.

(2) The form shall be made electronically available by the department and the health insurer.

(3) The completed form may also be electronically submitted from the prescribing provider to the health insurer.

(4) The department and the Department of Managed Health Care shall develop the form with input from interested parties from at least one public meeting.

(5) The department and the Department of Managed Health Care, in development of the standardized form, shall take into consideration the following:

(A) Existing prior authorization forms established by the federal Centers for Medicare and Medicaid Services and the State Department of Health Care Services.

(B) National standards pertaining to electronic prior authorization.

(e) A prescribing provider may use an electronic prior authorization system utilizing the standardized form described in subdivision (c) or an electronic process developed specifically for

transmitting prior authorization information that meets the National Council for Prescription Drug Programs' SCRIPT standard for electronic prior authorization transactions.

(f) Subdivision (a) does not apply if any of the following occurs:

(1) A contracted physician group is delegated the financial risk for the pharmacy or medical drug benefit by a health insurer.

(2) A contracted physician group uses its own internal prior authorization process rather than the health insurer's prior authorization process for the health insurer's insureds.

(3) A contracted physician group is delegated a utilization management function by the health insurer concerning any prescription drug, regardless of the delegation of financial risk.

(g) For prescription drugs, prior authorization requirements described in subdivisions (c) and (e) apply regardless of how that benefit is classified under the terms of the health insurer's group or individual policy.

(h) A health insurer shall maintain a process for an external exception request review that complies with subdivision (c) of Section 156.122 of Title 45 of the Code of Federal Regulations.

(i) For an individual, small group, or large group health insurance policy, a health insurer that provides coverage for outpatient prescription drugs shall comply with subdivision (c) of Section 156.122 of Title 45 of the Code of Federal Regulations.

(j) For purposes of this section:

(1) "Prescribing provider" shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an insured.

(2) "Exigent circumstances" exist when an insured is suffering from a health condition that may seriously jeopardize the insured's life, health, or ability to regain maximum function or when an insured is undergoing a current course of treatment using a nonformulary drug.

(3) "Completed prior authorization request" means a completed uniform prior authorization form developed pursuant to subdivision (c), or a completed request submitted using an electronic prior authorization system described in subdivision (e), or, for contracted physician groups described in subdivision (f), the process used by the contracted physician group.

(4) "Step therapy exception" means a step therapy protocol that is overridden in favor of immediate coverage of the prescription drug prescribed by a health care provider.

SEC. 5. Section 10123.197 of the Insurance Code is amended to read:

10123.197. (a) A request for an exception to a health insurer's step therapy process for prescription drugs may be submitted in the same manner as a request for prior authorization for prescription drugs pursuant to Section 10123.191, and shall be treated in the same manner, and shall be responded to by the health insurer in the same manner, as a request for prior authorization for prescription drugs.

(b) The department and the Department of Managed Health Care shall include a provision for step therapy exception requests in the uniform prior authorization form developed pursuant to subdivision (c) of Section 10123.191.

(c) "Step therapy exception" means a step therapy protocol that is overridden in favor of immediate coverage of the prescription drug prescribed by a health care provider.

SEC. 6. Section 10123.201 of the Insurance Code is amended to read:

10123.201.(a) A policy of health insurance that covers outpatient prescription drugs shall cover medically necessary drugs. The policy may provide for step therapy and prior authorization consistent with Section 1342.7 of the Health and Safety Code and any regulations adopted pursuant to that section.

- (b) (1) Commencing January 1, 2017, an insurer shall maintain a pharmacy and therapeutics committee that shall be responsible for developing, maintaining, and overseeing any drug formulary list. If the insurer delegates responsibility for the formulary to any entity, the obligation of the insurer to comply with this part shall not be waived.
- (2) The pharmacy and therapeutics committee board membership shall conform with both of the following:
- (A) Represent a sufficient number of clinical specialties to adequately meet the needs of insureds.
- (B) Consist of a majority of individuals who are practicing physicians, practicing pharmacists, and other practicing health professionals who are licensed to prescribe drugs.
- (3) Members of the board shall abstain from voting on any issue in which the member has a conflict of interest with respect to the issuer or a pharmaceutical manufacturer.
- (4) At least 20 percent of the board membership shall not have a conflict of interest with respect to the issuer or any pharmaceutical manufacturer.
- (5) The pharmacy and therapeutics committee shall meet at least quarterly and shall maintain written documentation of the rationale for its decisions regarding the development of, or revisions to, the formulary drug list.
- (6) The pharmacy and therapeutics committee shall do all of the following:
- (A) Develop and document procedures to ensure appropriate drug review and inclusion.
- (B) Base clinical decisions on the strength of the scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other related information.
- (C) Consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary drugs.
- (D) Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange.
- (E) Evaluate and analyze treatment protocols and procedures related to the insurer's formulary at least annually.
- (F) Review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered drug.
- (G) Review new United States Food and Drug Administration-approved drugs and new uses for existing drugs.
- (H) Ensure the insurer's formulary drug list or lists cover a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states and does not discourage enrollment by any group of insureds.
- (I) Ensure the insurer's formulary drug list or lists provide appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.
- (7) This subdivision shall be interpreted consistent with federal guidance issued under paragraph (3) of subdivision (a) of Section 156.122 of Title 45 of the Code of Federal Regulations. This subdivision shall apply to the individual, small group, and large group markets.
- (c) (1) A health insurer may impose prior authorization requirements on prescription drug benefits, consistent with the requirements of this part.
- (2) (A) If there is more than one drug that is appropriate for the treatment of a medical condition, a health insurer may require step therapy.

(B) If an insured is changing policies, the new policy shall not require an insured to repeat step therapy if that insured is already being treated for a medical condition by a prescription drug, provided that the drug is appropriately prescribed and is considered safe and effective for the insured's condition. This section shall not preclude the new policy from imposing a prior authorization requirement pursuant to subdivision (a) for the continued coverage of a prescription drug prescribed pursuant to step therapy imposed by the former policy, or preclude the prescribing provider from prescribing another drug covered by the new policy that is medically appropriate for the insured.

(C) A step therapy exception shall be expeditiously granted if any of the following criteria are met:

(i) The required prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the insured.

(ii) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the insured and the known characteristics of the prescription drug regimen.

(iii) The insured has tried the required prescription drug, or another prescription drug in the same pharmacologic class or with the same mechanism of action, while covered by their current or previous health insurance policy or health benefit plan contract, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(iv) The required prescription drug is not in the best interest of the insured, based on medical necessity.

(v) The insured is stable on a prescription drug selected by their health care provider for the medical condition under consideration while covered by their current or previous health insurance policy or health care service plan contract.

(D) This section does not prohibit either of the following:

(i) An insurer, health benefit plan, or utilization review organization from requiring an insured to try an AB-rated generic equivalent before providing coverage for the equivalent branded prescription drug.

(ii) A health care provider from prescribing a prescription drug that is determined to be medically appropriate.

(3) An insurer shall provide coverage for the medically necessary dosage and quantity of the drug prescribed for the treatment of a medical condition consistent with professionally recognized standards of practice.

(4) For plan years commencing on or after January 1, 2017, an insurer that provides essential health benefits shall allow an insured to access prescription drug benefits at an in-network retail pharmacy unless the prescription drug is subject to restricted distribution by the United States Food and Drug Administration or requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy. A nongrandfathered individual or small group health insurer may charge an insured a different cost sharing for obtaining a covered drug at a retail pharmacy, but all cost sharing shall count toward the policy's annual limitation on cost sharing consistent with Section 10112.28.

(d) An insured or the insured's designee, guardian, primary care physician, or health care provider may file an appeal of a prior authorization or the denial of a step therapy exception request. A health insurer shall designate a clinical peer to review appeals, because these appeals pertain to medical or clinical matters and an appeal must be reviewed by an appropriate health care professional. A clinical peer reviewing an appeal shall not have had any involvement in the initial determination that is the subject of the appeal.

- (e) Every health insurer that provides prescription drug benefits shall maintain all of the following information, which shall be made available to the commissioner upon request:
- (1) The complete drug formulary or formularies of the insurer, if the insurer maintains a formulary, including a list of the prescription drugs on the formulary of the insurer by major therapeutic category with an indication of whether any drugs are preferred over other drugs.
 - (2) Records developed by the pharmacy and ~~therapeutic~~ *therapeutics* committee of the insurer, or by others responsible for developing, modifying, and overseeing formularies, including medical groups, individual practice associations, and contracting pharmaceutical benefit management companies, used to guide the drugs prescribed for the insureds of the insurer, that fully describe the reasoning behind formulary decisions.
 - (3) Any insurer arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, contracting pharmaceutical benefit management companies, or other entities that are associated with activities of the insurer to encourage formulary compliance or otherwise manage prescription drug benefits.
- (f) The health insurer or utilization review organization shall report the following information to the department annually, in a format prescribed by the department:
- (1) The number of step therapy exception requests and prior authorization requests received.
 - (2) The type of health care providers or the medical specialties of the health care providers submitting requests.
 - (3) The number of step therapy exception requests that were initially denied and the reasons for the denials.
 - (4) The number of step therapy exception requests that were initially approved.
 - (5) The number of step therapy exception denials that were reversed by an internal appeal or an external review.
- (g) If an insurer provides prescription drug benefits, the commissioner shall, as part of its market conduct examination, review the performance of the insurer in providing those benefits, including, but not limited to, a review of the procedures and information maintained pursuant to this section, and describe the performance of the insurer as part of its report issued as part of its market conduct examination.
- (h) The commissioner shall not publicly disclose any information reviewed pursuant to this section that is determined by the commissioner to be confidential pursuant to state law.
- (i) For purposes of this section, the following definitions shall apply:
- (1) “Authorization” means approval by the health insurer to provide payment for the prescription drug.
 - (2) “Clinical peer” means a health care professional who is in the same profession and the same or similar specialty as the health care provider who typically manages the medical condition, procedures, or treatment under review.
 - (3) “Step therapy” means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are to be prescribed.
 - (4) “Step therapy exception” means a step therapy protocol that is overridden in favor of immediate coverage of the prescription drug prescribed by a health care provider.
 - (5) “Utilization review organization” means an entity that conducts utilization review, other than a health insurer performing its own utilization review.

(j) Nonformulary prescription drugs shall include any drug for which an insured's copayment or out-of-pocket costs are different than the copayment for a formulary prescription drug, except as otherwise provided by law or regulation.

(k) This section shall not be construed to affect an insured's or policyholder's eligibility to submit a complaint to the department for review or to apply to the department for an independent medical review under Article 3.5 (commencing with Section 10169).

(l) This section shall not be construed to restrict or impair the application of any other provision of this part.

SEC. 7.

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

Studies of the effects of step therapy protocols and prior authorization were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, Business Source Complete, 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, International Network of Agencies for Health Technology Assessment, National Health Service Centre for Reviews and Dissemination, National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network.

The search was limited to abstracts of studies published in English and studies in the United States. The medical effectiveness search was limited to studies published from 2015 to present, because CHBRP had previously reviewed this literature using the same search terms in 2015 for the AB 374 analysis.

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.

The search was limited to studies published from 2015 to present because CHBRP had previously conducted thorough literature searches on these topics in 2015 for AB374 and in 2013 for AB 899. Of the 314 articles found in the literature review, 21 were reviewed for potential inclusion in this report on AB 2144, and 14 studies were included in the medical effectiveness review for this report. The medical effectiveness review also presents findings from the 15 studies that were previously identified in the 2015 CHBRP AB 374 report.

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*.³⁴ 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;

³⁴ Available at: http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

- Preponderance of evidence;
- Limited evidence;
- Inconclusive evidence; and
- Insufficient evidence.

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)

- Controlled Substances
- Drug Prescriptions
- Drug Therapy
- Essential Drugs
- Fail First
- Health Care Outcome and Process Assessment
- Health Care Services
- Health Insurance Reimbursement
- Health Services Accessibility
- Insurance
- Medications
- Overrides
- Pharmacotherapy
- Prescriptions
- Prior Authorization
- Quality Assessment
- Step Edit
- Step Therapy
- Usage
- Utilization

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

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as the contracted actuarial firm, Milliman, Inc.³⁵

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.³⁶

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

Analysis-Specific Caveats and Assumptions

This subsection discusses the caveats and assumptions relevant to specifically to an analysis AB 2144.

CHBRP assumes that there will be no increase or decrease in overall utilization of prescription medication due to AB 2144. The change in utilization is entirely due to moving from one particular medication to another within the same classification. CHBRP further assumed that enrollees subject to step therapy protocols and prior authorization protocols were equally likely to be granted an override request, regardless of how many medication in their particular plan were subject to utilization management protocols.

CHBRP relied upon formularies from plans representing 69.5% of commercial/CalPERS enrollees which identified medications subject to step therapy and prior authorization protocols, arranged by therapeutic class. CHBRP estimated the utilization per 1,000 enrollees and average allowed charge for the medication identified as subject to step therapy and prior authorization protocols, and for alternative medications within the same therapeutic class from the Milliman 2020 Commercial Health Cost Guidelines. All utilization rates and allowed charges were trended to 2021 levels.

Insofar as CHBRP recognizes the prevalence of step therapy protocols requiring multiple medications prior to access to the initially prescribed medication, this analysis assumed that granted overrides replace an average of 1.5 required prescription fills with an equal number of prescription fills of the initially prescribed medication.

CHBRP estimates that compliance with AB 2144 step therapy override protocols will increase utilization of medications subject to step therapy by approximately 0.87%. Among plans responding to the Carrier Survey, 92% of commercial/CalPERS enrollees have AB 2144-compliant step therapy and prior authorization protocols (either no medications subject to step therapy/prior authorization or all mandated override provisions are already in place). Enrollees in the remaining plans have access to one or more of the mandated override provisions, and so AB 2144 will expand their step therapy and prior authorization protections modestly.

CHBRP estimated the degree of noncompliance with AB 2144 among plans responding to the Carrier Survey by assigning a weight to each requirement imposed by the mandate and calculating the weighted average compliance. This approach was chosen to reflect the proportion of members impacted, and the degree to which they may be impacted, by various forms of noncompliance with the mandate. For

³⁵ CHBRP's authorizing statute, available at http://chbrp.com/CHBRP_authorizing_statute_2018_FINAL.pdf, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

³⁶ See method documents posted at http://chbrp.com/analysis_methodology/cost_impact_analysis.php; in particular, see *2019 Cost Analyses: Data Sources, Caveats, and Assumptions*.

example some requirements of AB 2144 apply generally to all members, whereas others apply only to new enrollees; some forms of noncompliance may present a permanent barrier to access to medication, whereas others would be temporary.

Determining Public Demand for the Proposed Mandate

This subsection discusses public demand for the benefits AB 2144 would mandate. Considering the criteria specified by CHBRP's authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

- 1) Considers the bargaining history of organized labor; and
- 2) Compares 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.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include cost-sharing arrangements for prescription treatment or service. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS currently 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 carriers 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

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of AB 2144 would have a substantially different impact on utilization of either the tests, treatments or services for which coverage was directly addressed, the utilization of any indirectly affected utilization, or both. CHBRP reviewed the literature and consulted content experts about the possibility of varied second year impacts and determined the second year's impacts of AB 2144 would be substantially the same as the impacts in the first year (see Table 1). Minor changes to utilization and expenditures are due to population changes between the first year postmandate and the second year postmandate.

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A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing researchers and analysts who are **Task Force Contributors** to CHBRP from UC that conduct much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, **Milliman**, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

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