

Key Findings:

Analysis of California Assembly Bill AB 374 Step Therapy Coverage

Summary to the 2015–2016 California State Legislature, April 2015



AT A GLANCE

Assembly Bill AB 374 (introduced February 2015) would require compliant override procedures when step therapy protocols (STPs) are applicable to an outpatient prescription drug (OPD) benefit.

- **Enrollees covered.** In 2016, approximately 24.6 million Californians will have state-regulated health insurance subject to AB 374.
- **EHBs.** AB 374 would not exceed EHBs, because the mandate is applicable to particular terms or conditions but does not require new benefit coverage.
- **Medical effectiveness.** CHBRP found insufficient evidence to conclude whether STP overrides affect health outcomes. The absence of evidence is not evidence of no effect.
- **Benefit coverage.** The terms and conditions of 27% of enrollees would change to become fully compliant with AB 374's override approval criteria.
- **Utilization.** Filled prescriptions would be unchanged, although use of initially prescribed drugs would increase and use of STP-required drugs would decrease. The change would affect expenditures because initially prescribed drugs are frequently more expensive than STP-required drugs.
- **Impact on expenditures.** CHBRP estimates that premium impacts related to an increase in approved override requests would be 0.008%.
- **Public Health.** Because there is insufficient evidence to link approved overrides and health outcomes, the public health impact is unknown. Note: insufficient evidence is not evidence of no effect.

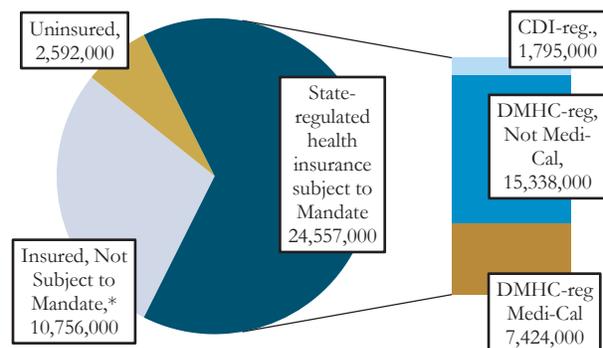
BACKGROUND

Step therapy protocols (STPs), which are also known as “fail first” protocols, are utilization management techniques applied to an enrollee’s outpatient prescription drug (OPD) benefit. When a drug subject to an STP is prescribed, the STP offers drug coverage, but requires that the enrollee try and fail one or more alternatives before coverage becomes available for the initially prescribed drug. STPs are frequently applied to expensive drugs, requiring use of less expensive substitutes. STP overrides may be requested. STP override requests generally require the prescriber to submit documentation as to why the override is justified.

BILL SUMMARY

In 2016, as noted in Figure 1, AB 374 would apply to the health insurance of 24.6 million Californians (all enrollees with health insurance potentially subject to state-level benefit mandates).

Figure 1. Health Insurance in CA and AB 374



*Federally regulated health insurance, such as Medicare, veterans, or self-insured plans.

Source: California Health Benefit Review Program, 2015.

AB 374 would require DMHC-regulated health plans and CDI-regulated policies that include both an outpatient

prescription drug (OPD) benefit and step therapy protocols (STPs) to grant step therapy overrides in five circumstances. The override is to be granted when the prescriber documents any/all of the following: that the STP-required drug 1) is contraindicated or likely to cause an adverse reaction (mental or physical harm) in the patient, 2) is expected to be ineffective due to the patient’s mental or physical characteristics, 3) is not medically appropriate, 4) is not FDA approved as a treatment for the patient’s condition; that 5) the patient is stable on the initially prescribed drug. AB 374 makes one broad exception in regard to these criteria, as AB 374 would not prohibit STPs from requiring use of an AB rated generic¹ before covering the initially prescribed drug. AB 374 also specifies that it would not affect cost-sharing terms and conditions.

IMPACT OF AB 374

CHBRP has found a wide variation in the presence of STPs for Californians enrolled in state-regulated health insurance. Not all enrollees have an OPD benefit and the presence of STPs varies. Approximately 3.0% of enrollees have no OPD benefit and 34.4% have an OPD benefit that is not subject to any STPs. Among the remaining 62.6% of enrollees, an OPD benefit is present and the number of drugs subject to STPs varies widely, from two to more than 100.

All enrollees with an OPD benefit subject to STPs have an override procedure. Postmandate, the terms of the override procedures would change for approximately 27% enrollees. Postmandate, AB 374 would alter the override criteria for some enrollees with an OPD benefit subject to STPs. AB 374 would require override approval when the prescriber documents that the STP-required drug is not medically appropriate. Currently, the override process might consider listing of the STP-required drug as proof of the drug being medically appropriate, but AB 734 would focus the request on prescriber documentation regarding medical appropriateness. The result would be an increase in approved override requests. Post mandate, AB 374

¹ The FDA considers category “A” drug products to be therapeutically equivalent to other pharmaceutically equivalent products and subcategory “AB” drug products to be those for which actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence. See FDA website www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm accessed on February 27, 2015.

would also prohibit consideration of information other than FDA approval when a prescriber requests an override and documents that the STP-required drug is not FDA-approved for the enrollee’s condition. Currently, the override process may consider other information (such as research literature indicating a common, safe and effective off-label use of the STP-required drug), but AB 374 would focus the request on FDA-approval. The result would be an increase in approved override requests.

CHBRP has assumed that the total number of filled prescriptions would not change, postmandate, because STPs offer coverage for an alternate drug. However, postmandate, STP overrides will increase from 8.7 per 1,000 enrollees to 9.0. CHBRP has assumed that additional approved override requests would decrease use of the STP-required drug, which is generally a less expensive drug and increase use of the initially prescribed drug (both drugs being in the same drug class). Expenditure impacts would be as indicated in Figure 2.

Figure 2. Expenditure Impacts of AB 374

Employer premium expenditures	\$5,013,000
Individual premium expenditures	\$2,948,000
Employee premium expenditures	\$1,260,000
Out-of-pocket expenses for covered benefits	\$1,614,000
Enrollee expenses for noncovered benefits	\$0
Net Change	\$10,835,000

MEDICAL EFFECTIVENESS AND PUBLIC HEALTH IMPACTS

CHBRP finds insufficient evidence to conclude that use of STPs or override protocols as described in AB 374 would change health outcomes. Therefore, the public health impact in the first year, postmandate, is unknown. Please note that the absence of evidence is not “evidence of no effect.” It is possible that an impact—positive or negative—could result, but current evidence is insufficient to provide an estimate.