SENATE THIRD READING
SB 427 (Portantino)
As Amended August 14, 2023
Majority vote

SUMMARY

Prohibits a nongrandfathered or grandfathered health plan contract or health insurance policy from imposing any cost-sharing or utilization review requirements for antiretroviral drugs, devices, or products (ARVs) that are either approved by the United States Food and Drug Administration (FDA) or recommended by the federal Centers for Disease Control and Prevention (CDC) for the prevention of human immunodeficiency virus (HIV)/ acquired immunodeficiency syndrome (AIDS). Prohibits a health plan or health insurer from subjecting ARVs that are either approved by the FDA or recommended by the CDC for the prevention HIV/AIDS, to prior authorization or step therapy, but authorizes prior authorization or step therapy if at least one therapeutically equivalent version is covered without prior authorization or step therapy and the insurer provides coverage for a noncovered therapeutic equivalent antiretroviral drug, device, or product without cost sharing pursuant to an exception request. Delays implementation of this bill for an individual and small group health plan contract or insurance policy until January 1, 2025.

COMMENTS

According to the California Health Benefits Review Program (CHBRP), HIV attacks the body's CD4 and/or T-cells (i.e., a type of white blood cell), which are integral to the body's immune function. HIV spreads via direct contact with certain bodily fluids of an individual with a detectable viral load. If undiagnosed and left untreated, HIV invades and effectively destroys CD4 cells during the virus replication process, leading to opportunistic infections, opportunistic cancers, and death. Without initial treatment and routine adherence to treatment, HIV typically progresses through three stages of disease: 1) acute HIV infection; 2) chronic HIV infection; and, 3) acquired immunodeficiency syndrome (AIDS). There is no cure for HIV/AIDS; however, with routine care and proper treatment, HIV-related morbidity and mortality can be prevented through the use of ARVs – known for inhibiting viral replication and allowing for immune reconstitution. Given the availability of ARVs, it is possible for people living with HIV to achieve a life expectancy similar to that of the general population.

1) *Antiretrovirals for Prevention of HIV/AIDS*. Preventing the transmission of HIV to the HIV-negative population has been the focus of a concerted United States (U.S.) public health effort for more than 30 years. Pre-exposure prophylaxis (PrEP) and postexposure prophylaxis (PEP) are an essential part of the HIV prevention toolbox, which also includes education, needle exchanges, and condom programs. Both strategies involve using ARVs to abort the establishment of chronic HIV infection. By protecting the cells, these medications eliminate the ability of HIV to replicate and destroy the immune system. The drug compounds used in PrEP and PEP regimens also may be used as part of a larger HIV treatment regimen.

2) *HIV Prevalence*. Ongoing Department of Public Health (DPH) HIV surveillance over the years indicates promising progress in the reduction of new HIV infections as part of a broader nationwide initiative launched by the U.S. Department of Health and Human Services in 2019. California witnessed declines in both the annual number and rate of new

HIV diagnoses over a four year period. From 2016 to 2020, the number of new HIV diagnoses declined by approximately 23% – from 5,140 in 2016 to 3,965 in 2020. Similarly, the rate of new diagnoses per 100,000 population declined by approximately 24%, from 13.1 to 9.9% during the same period. During the same four-year period (2016 to 2020), the number of persons living with HIV increased in California – from approximately 133,000 to more than 139,000 – indicating the effectiveness of initiating and sustaining ARV use.

According to CHBRP, this bill requires health plans and insurers to provide coverage for FDA-approved ARVs. Health plans would not need to cover all therapeutically equivalent versions without prior authorization or step therapy (i.e. UM techniques) if they provide coverage for a noncovered therapeutic equivalent ARVs drug/device/product without cost sharing. For nongrandfathered and grandfathered plans, this bill prohibits cost sharing and UM for FDA-approved or CDC-recommended ARVs drugs, devices, or products. It should be noted that at the time of CHBRP's analysis, there are no FDA-approved or CDC-recommended antiretroviral devices or products. As such, CHBRP's analysis below focuses only on antiretroviral drugs.

3) *CHBRP analysis.* CHBRP states the following in its analysis:

   a) *Enrollees covered.* At baseline, 100% (22,842,000) of enrollees with the Department of Managed Health Care (DMHC) or California Department of Insurance (CDI)-regulated health insurance plans/policies would have coverage subject to this bill. Of these, 98.9% have coverage for ARVs. At baseline, 38.6% of enrollees have coverage for ARVs that is fully compliant with this bill. Postmandate, 100% of enrollees with coverage subject to this bill would have coverage for ARVs without cost sharing. Although the benefit coverage for beneficiaries with DMHC-regulated Medi-Cal plans is subject to this bill, their pharmacy benefit is carved out and administered under Medi-Cal Rx, and therefore, this bill would not impact their benefit coverage. At baseline, CHBRP estimates that 130,731 enrollees per year in DMHC-regulated plans and CDI-regulated policies used ARVs with cost sharing. Among these, 49,257 enrollees per year used ARVs with cost sharing and 97,658 enrollees used ARVs with no cost sharing. It is important to note that these two groups had some overlap (16,184 enrollees), as some enrollees had cost sharing during the year until hitting their maximum out-of-pocket limit, and then had no cost sharing for the remainder of the year. On average, each enrollee with cost sharing had on average 7.6 prescriptions annually with cost sharing at baseline, with an average of 6.5 prescriptions for enrollees with no cost sharing. Postmandate, CHBRP estimates an additional 1,402 enrollees will utilize ARVs (equal to 132,133 enrollees overall), representing a 1% increase in enrollees using ARVs overall. On average, enrollees who use ARVs would obtain 7.7 prescriptions without cost sharing annually, per person. This translates to an overall utilization of 1,016,959 ARV prescriptions without cost sharing, postmandate, representing a 1% increase in ARV prescriptions.

   b) *Impact on expenditures.* This bill would increase total net annual expenditures by $51,601,000 or 0.0352% for enrollees with DMHC-regulated plans and CDI-regulated policies, excluding DMHC-regulated Medi-Cal.

      i) Medi-Cal. For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, there is no impact.

ii) CalPERS. For enrollees associated with CalPERS in DMHC-regulated plans, premiums would increase by 0.08% ($0.53 per member per month, or approximately $4.7 million total increase in expenditures).

iii) Number of Uninsured in California. Since the change in average premiums does not exceed 1% for any market segment, CHBRP expects no measurable change in the number of uninsured persons due to this bill.

c) *Medical effectiveness.* CHBRP reviewed findings from evidence on the effects of cost sharing and UM on ARVs (including PrEP and PEP) use and adherence for patients with HIV and those at risk of contracting HIV. CHBRP did not review literature on the effectiveness of ARVs because all ARVs have been approved by the FDA, and the efficacy of ARVs is well-established. CHBRP found the following:

i) Inconclusive evidence on the effect of cost sharing for ARVs (including PrEP and PEP) on long-term adherence and viral suppression for people living with HIV.

ii) Insufficient evidence on the effect of cost sharing for ARVs (including PrEP and PEP) on health care utilization and health outcomes; and,

iii) Insufficient evidence on the effect of UM for ARVs (including PrEP and PEP) health care utilization and health outcomes.

According to the Author
The HIV epidemic continues to disproportionately affect historically disadvantaged communities in California. Cost and access are two major barriers to lifesaving medications. The only way to end the HIV epidemic is by ensuring effective HIV prevention and treatment reaches all communities, but especially those disproportionately affected by HIV. HIV PrEP and PEP are important for the overall health of many at-risk and historically disadvantaged communities. The author states that under this bill all grandfathered health insurance policies and health plans would be required to cover both HIV PrEP and PEP without any cost sharing, and in doing so, this bill would expand zero-dollar coverage of PrEP to one million Californians who must currently pay out-of-pocket for PrEP. In addition, the author concludes that non-grandfathered health insurance policies and health plans would be required to cover PEP without cost sharing.

Arguments in Support
CDI Commissioner Ricardo Lara, sponsor, writes that the HIV epidemic continues to disproportionately impact historically disadvantaged communities in California. In addition, cost and access are two major barriers to lifesaving medications. DPH's 2020 Health Disparities Report found the following: Black/African Americans are the most disproportionately affected by HIV making up 17% of California's HIV positive population, but only around 6% of California's total population; and, Latinx people make up the largest racial/ethnic group among new HIV diagnoses, accounting for 50% of all new HIV diagnoses, but only around 40% of California's population. Transmission by male-to-male sexual contact, including male-to-male sexual contact and injection drug use, make up the majority of the HIV positive population in California, accounting for 60% of new HIV diagnoses and 73% of all living HIV cases in 2020. In California, rates of HIV infection among transgender people are unknown, but transgender women are among the groups most affected by HIV. Nationally, HIV prevalence among transgender people is around 9.2%. Prevention efforts have been frustrated by, in part, limited access to health coverage. Health coverage plays a major role in enabling people to access health

care and protecting families from high medical costs. Persons of color have faced longstanding disparities in health coverage that contribute to disparities in health. Persons from racial and ethnic groups are more likely to be uninsured compared to non-Hispanic whites, limiting their access to health care. CDI concludes that other barriers to health care access include lack of transportation and childcare, inability to take time off work, experiences with housing instability or homelessness, communication and language barriers, racism, discrimination, and lack of trust in health care providers.

Arguments in Opposition
The California Association of Health Plans (CAHP), the Association of California Life and Health Insurance Companies (ACLHIC), and America's Health Insurance Plans (AHIP) write that state mandates increase costs of coverage – especially for families who buy coverage without subsidies, small business owners who cannot or do not wish to self-insure, and California taxpayers who foot the bill for the state's share of those mandates. When considering the forthcoming analyses from CHBPR on these bills, CAHP, ACLHIC, and AHIP urge legislators to also consider the cumulative impacts that these mandates may have on premiums and access to coverage. All of these bills will increase costs and limit flexibility for employers. Faced with higher costs, employers must make difficult decisions about whether to absorb premium increases or seek alternative coverage options.

FISCAL COMMENTS

According to the Assembly Appropriations Committee:

1) No costs to CDI.

2) DMHC estimates costs of this bill to be approximately $55,000 in fiscal year 2025-26 and $133,000 in FY 2026-27 and annually thereafter (Managed Care Fund).

3) The Department of Health Care Services (DHCS) expects this bill to shift costs from fee-for-service Medi-Cal to Medi-Cal Managed Care (MCMC). That shift in costs would be approximately $600 million ($300 million General Fund, $300 million federal funds).

   As this bill would shift responsibility for ARVs from fee-for-service to MCMC, DHCS anticipates no change in utilization. DHCS would also continue to collect federal mandatory rebates on any shift of utilization to MCMC. However, DHCS would lose supplemental rebates for utilization that shifted to MCMC. If 85% of claims went to MCMC, the loss of supplemental rebates would be approximately $45 million to $50 million annually (General Fund, federal funds).

4) CHBRP estimates an increase in CalPERS employer premiums of $4.7 million, of which the state pays approximately 60% (Public Employees Health Care Fund).

VOTES

SENATE FLOOR: 33-1-6
YES: Allen, Archuleta, Ashby, Atkins, Becker, Blakespear, Bradford, Caballero, Cortese, Dodd, Durazo, Eggman, Glazer, Gonzalez, Hurtado, Laird, Limón, McGuire, Menjivar, Min,

Newman, Ochoa Bogh, Padilla, Portantino, Roth, Rubio, Skinner, Smallwood-Cuevas, Stern, Umberg, Wahab, Wiener, Wilk
NO: Jones
ABS, ABST OR NV: Alvarado-Gil, Dahle, Grove, Nguyen, Niello, Seyarto

ASM HEALTH: 12-0-3
YES: Wood, Waldron, Aguiar-Curry, Arambula, Boerner, Wendy Carrillo, Maienschein, McCarty, Rodriguez, Santiago, Villapudua, Weber
ABS, ABST OR NV: Flora, Vince Fong, Joe Patterson

ASM APPROPRIATIONS: 13-1-2
YES: Holden, Bryan, Calderon, Wendy Carrillo, Mike Fong, Hart, Lowenthal, Mathis, Papan, Pellerin, Soria, Weber, Wilson
NO: Dixon
ABS, ABST OR NV: Megan Dahle, Sanchez

UPDATED

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