California Health Benefits Review Program

Analysis of California Assembly Bill 2516
Health Care Coverage: Human Papillomavirus

A Report to the 2021–2022 California State Legislature

April 15, 2022

CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Key Findings

Analysis of California Assembly Bill 2516
Health Care Coverage: Human Papillomavirus

Summary to the 2021–2022 California State Legislature, April 15, 2022

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

SUMMARY

The version of California Assembly Bill (AB) 2516 analyzed by CHBRP would require DMHC-regulated plans and CDI-regulated policies to provide coverage for the human papillomavirus (HPV) vaccine for enrollees for whom it is approved by the FDA. Plans and policies would be prohibited from charging cost sharing for the HPV vaccine. The bill would also expand comprehensive clinical family planning services under the Family Planning, Access, Care, and Treatment (Family PACT) program to include the HPV vaccine for enrollees for whom the vaccine is approved by the FDA.

In 2023, of the 22.8 million Californians enrolled in state-regulated health insurance, all of them would have insurance subject to AB 2516.

Benefit Coverage: At baseline, 99.6% of enrollees have coverage that is fully compliant with AB 2516. The 0.41% of enrollees without coverage are enrolled in grandfathered health plans and policies. Postmandate, 100% of enrollees would have coverage for the HPV vaccine with no cost sharing. AB 2516 does not exceed the definition of essential health benefits (EHBs) in California.

Medical Effectiveness: For females vaccinated at age 26 or younger, CHBRP found *clear and convincing evidence* that the HPV vaccine is effective against high-grade cervical intraepithelial neoplasia (CIN), adenocarcinoma in situ (AIS), and cervical cancer. For females vaccinated after age 26, there is *limited evidence* that the HPV vaccine is effective against cervical lesions. There is *insufficient evidence* that HPV vaccines reduce the overall incidence of oral or oropharyngeal cancers after vaccination at any age. CHBRP found a *preponderance of evidence* that the HPV vaccine is effective at providing protection against HPV-related anogenital disease for males vaccinated at any age, and *clear and convincing evidence* the vaccine protects against genital warts in females and males vaccinated at age 26 or younger.

Cost and Health Impacts[1]: In 2023, AB 2516 would increase total net annual expenditures by $3,834,000 or 0.0026% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a $3,975,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a decrease of $141,000 in enrollee cost-sharing for covered benefits.

Due to minimal changes in utilization of the HPV vaccine, CHBRP concludes that passage of AB 2516 would have no measurable short-term public health impact. The long-term public health impacts are mostly isolated to enrollees aged 9 to 26 years in grandfathered plans or policies who later received the vaccine due to the elimination of cost sharing. The larger population may benefit from reduced transmission of the disease in the larger community.

CONTEXT

Human papillomavirus (HPV) is a group of more than 200 viruses, 14 of which have been identified as high-risk and are associated with several types of cancers, including nearly all cervical cancers, and most anal, vaginal, penile, vulvar, head, and neck cancers. Depending on the type of HPV and the immune system of the individual, infection can cause no symptoms at all and completely resolve, lead to the development of genital warts, or persist and potentially develop into precancerous cell changes or cancer in later life.[2]

HPV is usually spread through sexual activity with an infected partner. It is the most common sexually transmitted infection in the United States, with an estimated 13 million new cases each year and will infect approximately 85% of the population at some point in their lifetime. Most individuals have been infected with HPV by age 27, and for this reason the HPV vaccine is recommended primarily for those aged 11 to 12 years, as the vaccine is most effective for individuals who have not yet been exposed to the virus (often occurring soon after initiating sexual activity).

[1] Similar cost and health impacts could be expected for the following year, though possible changes in medical science and other aspects of health make stability of impacts less certain as time goes by.

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

The FDA has approved three HPV vaccines for use in the United States. Gardasil® has been approved for use in females and males aged 9 to 26 years, Gardasil® 9 has been approved for use in females and males aged 9 to 45 years, and Cervarix™ has been approved for use in females aged 9 to 25 years. However, only Gardasil® 9 is available on the market. Since FDA approval of the HPV vaccine in 2006, HPV infections associated with genital warts and most HPV-related cancers have dropped 88% among adolescent females and 81% among adult females, and cervical precancerous changes have decreased 40% among adult females.

The Affordable Care Act (ACA) requires nongrandfathered group and individual health plans and policies to provide coverage without cost sharing for certain preventive services, including those recommended by the Advisory Committee on Immunization Practices (ACIP). ACIP currently recommends HPV vaccination at age 11 or 12, although vaccination may begin at age 9. Catch-up HPV vaccination is also recommended for all individuals through age 26. For adults aged 27 to 45 years, ACIP recommends shared clinical decision-making for potential HPV vaccination.

BILL SUMMARY

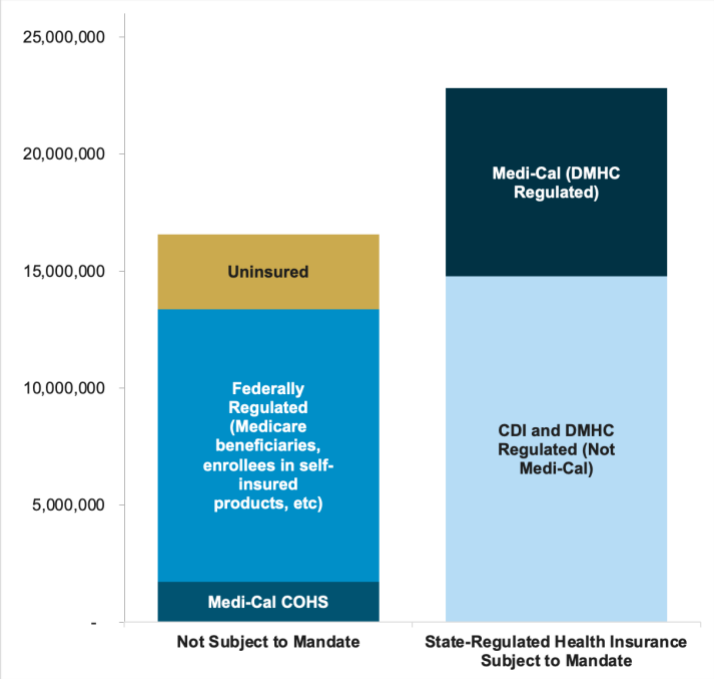
AB 2516 would require DMHC-regulated plans and CDI-regulated policies to provide coverage for the human papillomavirus (HPV) vaccine for enrollees for whom it is approved by the FDA. Plans and policies would be prohibited from charging cost sharing for the HPV vaccine. AB 2516 would also expand comprehensive clinical family planning services under the Family PACT program to include the HPV vaccine for enrollees for whom the vaccine is approved by the FDA.

Figure A notes how many Californians have health insurance that would be subject to AB 2516 (approximately 57.3% of Californians).

Family PACT

Family PACT is a limited benefit program that provides Californians with incomes below 200% of the federal poverty level (FPL) and no other coverage for family planning services access to free family planning services, sexually transmitted infection testing and treatment, cervical cancer screening, and limited fertility services. In 2019, Family PACT provided services to 695,245 individuals.

Figure A. Health Insurance in CA and AB 2516



Source: California Health Benefits Review Program, 2022.

IMPACTS

Benefit Coverage, Utilization, and Cost

Benefit Coverage

CHBRP estimates that, at baseline, 99.6% of enrollees in DMHC-regulated plans and CDI-regulated policies have coverage of the HPV vaccine without cost sharing. Enrollees without coverage or coverage with cost sharing for the HPV vaccine have DMHC-regulated plans or CDI-regulated policies that are "grandfathered" under the provisions of the ACA, and so are able to retain cost sharing for vaccinations. Postmandate, 100% of enrollees would have coverage for HPV vaccines with no cost sharing.

Utilization

At baseline, there are 120.9 HPV vaccine shots per 1,000 female enrollees aged 9 to 26 years, and there are 113 HPV vaccines per 1,000 male enrollees aged 9 to 26 years. Among those aged 27 to 45 years, there are 6.1 HPV vaccines per 1,000 female enrollees and 4.4 HPV vaccines per 1,000 male enrollees.

Postmandate, utilization for females and males aged 9 to 26 years would increase slightly, as the utilization rate

for the 0.4% of enrollees in DMHC-regulated plans or CDI-regulated policies who previously had cost sharing would increase to match those who did not have cost sharing at baseline. CHBRP estimates that the resulting new average utilization would increase by 1.5 per 1,000 enrollees from 120.9 to 122.3 for females aged 9 to 26 years and by 1.3 from 113 to 114.4 for males aged 9 to 26 years. CHBRP estimates that the change in benefit coverage and reduction in cost sharing for those aged 27 to 45 years would result in no measurable in utilization since the medical guidelines for shared clinical decision-making will keep utilization down to those who are both medically eligible and want to obtain the series of HPV vaccination shots. Postmandate, the average utilization rate for the HPV vaccine for both males and females aged 27 to 45 years will have no measurable change.

Among enrollees with coverage at baseline, cost sharing was present for 0.7 vaccine injections per 1,000 females aged 9 to 26 years, 1.1 vaccines per 1,000 males aged 9 to 26 years, 0.1 vaccines per 1,000 females aged 27 to 45 years, and 0.2 vaccines per 1,000 males aged 27 to 45 years. Postmandate, no enrollees would have cost sharing for HPV vaccine shots. This equates to approximately 9,400 vaccine shots that had cost sharing for HPV vaccines at baseline.

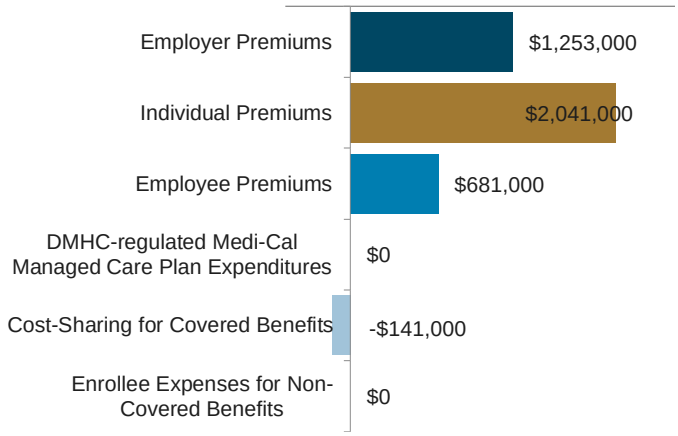
Expenditures

AB 2516 would increase total net annual expenditures by $3,834,000 or 0.0026% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a $3,975,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a decrease of $141,000 in enrollee expenses for covered and/or noncovered benefits.

Changes in expenditures are due to (1) a shift of cost sharing for enrollees with cost sharing at baseline to no cost sharing postmandate and (2) new utilization of the HPV vaccine.

For enrollees with cost sharing at baseline, average annual out-of-pocket expense reductions range between $102 and $262. Cost sharing amounts are dependent upon an enrollee's plan or policy design. For the enrollees with cost sharing, on average, 81% is due to deductible, 17% is due to coinsurance, and 2% is due to copayments.

Figure B. Expenditure Impacts of AB 2516



Source: California Health Benefits Review Program, 2022.

Medi-Cal

Medi-Cal provides coverage without cost sharing for the HPV vaccine at baseline. As such, no impact on this population by AB 2516 is projected.

CalPERS

CalPERS provides coverage without cost sharing for the HPV vaccine at baseline. As such, no impact on this population by AB 2516 is projected.

Covered California – Individually Purchased

Individually purchased Covered California plans or policies provide coverage for the HPV vaccine at baseline. As such, no impact on this population by AB 2516 is projected.

Family PACT

CHBRP is unable to estimate how many Family PACT enrollees are vaccinated with the HPV vaccine at baseline, and how many future enrollees would receive this service should AB 2516 pass.

Number of Uninsured in California

Because the change in average premiums does not exceed 1% for any market segment, CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 2516.

Medical Effectiveness

CHBRP examined literature on the clinical effectiveness of the HPV vaccine for preventing HPV-related cancers and HPV-related genital warts in both females and males.

CHBRP found there is:

- *Clear and convincing evidence*[3] that the HPV vaccine is effective at preventing high-grade cervical intraepithelial neoplasia (CIN), adenocarcinoma in situ (AIS), and cervical cancer for females vaccinated at age 26 or younger, and at preventing HPV-related anogenital warts for both females and males vaccinated at age 26 or younger.
- *Preponderance of evidence*[4] that the HPV vaccine is effective at preventing HPV-related anogenital disease for males vaccinated at age 26 or younger.
- *Limited evidence*[5] that the HPV vaccine is effective at preventing cervical lesions for females vaccinated at age 27 or older.
- *Insufficient evidence*[6] that the HPV vaccine is effective at preventing oral or oropharyngeal HPV infections for females and males vaccinated at any age, as well as for preventing genital warts for females males vaccinated at age 27 or older.

Table A provides a visual summary of CHBRP's evidence findings by age at vaccination and infection/disease type.

Table A. Summary of Effectiveness of the HPV Vaccine in Preventing HPV Infection and Related Cancers, by Age at Vaccination

	Vaccinated at age 26 or younger	Vaccinated at age 27 or older
Cervical cancer (females)	Clear and convincing evidence, effective	Limited evidence, effective
CIN (females)	Clear and convincing evidence, effective	Limited evidence, effective
AIS (females)	Clear and convincing evidence, effective	Limited evidence, effective
Oral or oropharyngeal infections (females/males)	Insufficient evidence	Insufficient evidence
Anogenital disease (males)	Preponderance of evidence, effective	Preponderance of evidence, effective
Anogenital warts (females/males)	Clear and convincing evidence, effective	Insufficient evidence

Source: California Health Benefits Review Program, 2022.
Notes: Anogenital diseases include anal intraepithelial neoplasia (AIN) and anal cancer. Anogenital warts are the same as genital warts.
Key: AIS= adenocarcinoma in situ; CIN= high-grade cervical intraepithelial neoplasia.

Public Health

In the first year postmandate, CHBRP projects AB 2516 will have no measurable impact on public health. Postmandate, approximately 4,078 additional vaccinations would occur among male enrollees and 4,367 additional vaccinations would occur among female enrollees aged 9 to 26 years because of increased coverage and reduced cost sharing. Although the HPV vaccine is found to be medically effective, CHBRP concludes that passage of AB 2516 would have no measurable short-term public health impact due to

[3] *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.
[4] *Preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.
[5] *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.
[6] *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.

minimal change in overall utilization and lack of manifest of vaccine effects in the short term. For this reason, CHBRP also concludes that AB 2516 would have no measurable impact on disparities in vaccination status or health outcomes (by sex, race/ethnicity, or sexual orientation/gender identity). It also would have no measurable impact on premature death and societal economic losses.

At the person level, one potentially detectable vaccine impact in the first year following vaccination would be a potential reduction in genital warts.

While elimination of cost sharing eliminates a barrier for a small group of enrollees who currently are subject to cost sharing, other barriers to HPV vaccination may continue to persist postmandate. These may include prior authorization requirements, transportation issues to complete the entire vaccine series, parental disagreement about whether or not a minor enrollee should receive the vaccine, or individual decisions not to receive the vaccine.

Long-Term Impacts

CHBRP estimates that increases in utilization of the HPV vaccine among enrollees in grandfathered plans or policies and who had cost sharing at baseline will lead to future decreases in cervical cancer, as well as other HPV-related genital diseases. The decreases in HPV-related disease and cancer would lead to decreases in tests, treatments, and services related to these conditions over time. Reductions in the incidence of HPV-related diseases will be associated with decreases in costs of tests, treatments, and services related to those conditions.

Due to minimal changes in utilization of the HPV vaccine, CHBRP concludes that passage of AB 2516 would have no measurable long-term public health impact. The long-term public health impacts are mostly isolated to enrollees aged 9 to 26 years in grandfathered plans or policies who later received the vaccine due to the elimination of cost sharing. The larger population may benefit from reduced transmission of HPV infections in the larger community.

One provision of AB 2516 that could not be quantified by CHBRP was the expansion of services covered in Family PACT. Because Family PACT primarily serves low-income persons of color in California regardless of immigration status, there is the potential to increase vaccination rates among this population. However, the extent to which vaccination rates would increase and the resulting impact on disparities and social determinants of health is unknown.

Essential Health Benefits and the Affordable Care Act

The HPV vaccine is currently covered by California's EHB benchmark plan and is recommended by ACIP. Therefore, AB 2516 appears not to exceed the definition of EHBs in California.

A Report to the California State Legislature

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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.

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Table 1. Impacts of AB 2516 on Benefit Coverage, Utilization, and Cost, 2023

	Baseline (2023)	Postmandate Year 1 (2023)	Increase/ Decrease	Change Postmandate
Benefit Coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	22,810,000	22,810,000	0	0.00%
Total enrollees with health insurance subject to AB 2516	22,810,000	22,810,000	0	0.00%
Total enrollees with coverage fully compliant with AB 2516	22,717,611	22,810,000	92,389	0.41%
Total percentage of enrollees with coverage fully compliant with AB 2516	99.6%	100.0%	0.4%	0.41%
Utilization and Cost				
Number of HPV vaccine shots per 1,000 enrollees				
Male, Aged 9-26	113.0	114.4	1.3	1.19%
Female, Aged 9-26	120.9	122.3	1.5	1.22%
Male, Aged 27-45	4.4	4.4	0.0	0.00%
Female, Aged 27-45	6.1	6.1	0.0	0.00%
Number of HPV vaccine shots w/cost sharing per 1,000 enrollees				
Male, Aged 9-26	1.1	0.0	(1.1)	-100.00%
Female, Aged 9-26	0.7	0.0	(0.7)	-100.00%
Male, Aged 27-45	0.2	0.0	(0.2)	-100.00%
Female, Aged 27-45	0.1	0.0	(0.1)	-100.00%
Per unit cost of HPV vaccines				
Commercial and CalPERS	$360.66	$360.66	$0.00	0.00%
DMHC-regulated Medi-Cal managed care	$110.09	$110.09	$0.00	0.00%
Cost sharing per HPV vaccine among users w/non-zero cost share				
Aged 9-45	$157.80	$0.00	($157.80)	-100.00%
Expenditures				
Premium (expenditures) by payer				
Private Employers for group insurance	$52,967,575,000	$52,968,828,000	$1,253,000	0.0024%
CalPERS HMO employer expenditures (b) (c)	$5,895,476,000	$5,895,476,000	$0	0.0000%
Medi-Cal Managed Care Plan expenditures	$25,989,411,000	$25,989,411,000	$0	0.0000%
Enrollee premiums (expenditures)				
Enrollees for individually purchased insurance	$24,029,788,000	$24,031,829,000	$2,041,000	0.0085%
Individually Purchased – Outside Exchange	$6,324,312,000	$6,326,353,000	$2,041,000	0.0323%
Individually Purchased – Covered California	$17,705,476,000	$17,705,476,000	$0	0.0000%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal managed care (c)	$24,504,936,000	$24,505,617,000	$681,000	0.0028%
Enrollee out-of-pocket expenses				
Cost sharing for covered benefits (deductibles, copayments, etc.)	$15,807,011,000	$15,806,870,000	-$141,000	-0.0009%
Expenses for noncovered benefits (d) (e)	$0	$0	$0	0.00%
Total Expenditures	$149,194,197,000	$149,198,031,000	$3,834,000	0.0026%

Source: California Health Benefits Review Program, 2022.

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.[7]

(b) Approximately 51.7% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(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 covered by insurance at baseline. 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 = California Public Employees' Retirement System; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; HMO = Health Maintenance Organizations

[7] For more detail, see CHBRP's *Estimates of Sources of Health Insurance in California for 2023*, a resource 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)[8] conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 2516, Health Care Coverage: Human Papillomavirus.

Bill-Specific Analysis of AB 2516, Health Care Coverage: Human Papillomavirus

Bill Language

AB 2516 would require health plans regulated by the California Department of Managed Health Care (DMHC) and policies regulated by the California Department of Insurance (CDI) to provide coverage for the human papillomavirus (HPV) vaccine for enrollees for whom the vaccine is approved by the U.S. Food and Drug Administration (FDA). Plans and policies would be prohibited from charging cost sharing for the HPV vaccine, defined as deductible, coinsurance, or copayment.

The bill would also expand comprehensive clinical family planning services under the Family Planning, Access, Care, and Treatment (Family PACT) program to include the HPV vaccine for enrollees for whom the vaccine is approved by the FDA.

The full text of AB 2516 can be found in Appendix A.

Relevant Populations

If enacted, AB 2516 would apply to the health insurance of approximately 22,810,000 enrollees (57.3% of all Californians). This represents 100% of Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law, which includes health insurance regulated by DMHC or CDI. If enacted, the law would apply to the health insurance of enrollees in DMHC-regulated plans and CDI-regulated policies, including DMHC-regulated Medi-Cal managed care plans.

In 2019, Family PACT served 695,245 persons (CHHS, 2021).

Family PACT

Family PACT is a limited benefit program that provides Californians with incomes below 200% of the federal poverty level (FPL) and no other coverage for family planning services access to free family planning services, sexually transmitted infection testing and treatment, cervical cancer screening, and limited fertility services.[9] The program is administered by the Department of Health Care Services' (DHCS) Office of Family Planning and funded through a combination of state and federal dollars, including reimbursement from Medi-Cal and appropriations from California's General Fund. Providers are reimbursed on a fee-for-service basis. The number of people Family PACT serves each fiscal year has been decreasing steadily since the passage of the Affordable Care Act and related coverage expansions, as well as since expansion of Medi-Cal to certain income-eligible populations without documentation. As California continues to expand full-scope coverage through Medi-Cal to the remaining income-eligible Californians without documentation (Governor Newsom's 2022–2023 draft budget proposes expanding Medi-Cal to income-eligible adults aged 27 to 49 years in January 2024), the number of persons served through Family PACT will likely continue to decrease.

[8] CHBRP's authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.
[9] Family PACT. http://familypact.org/

In fiscal year 2016–2017, 9% of clients had incomes between 139% and 200% FPL (DHCS, 2020b). This group likely represents Californians without documentation who are ineligible for subsidies through Covered California. Moving forward, Family PACT will continue to provide family planning services to those who are uninsured, including those ineligible for Medi-Cal or other heavily subsidized insurance, those who are underinsured, and income-eligible minors.[10]

The HPV vaccine is not a service currently provided by Family PACT (DHCS, 2020a).

Interaction with Existing State and Federal Requirements

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

California Policy Landscape

California law and regulations

In 2020, the California Legislature introduced legislation to expand comprehensive clinical family planning services under the Family PACT program to include the HPV vaccine.[11]

Governor Newsom's budget proposal for 2022–23 includes $8 million total funds to expand the Family PACT program to include the HPV vaccine for persons aged 19 to 45 years (DHCS, 2022).

In 1996, California established the Family PACT program under the DHCS.[12] DHCS also manages the breast and cervical cancer treatment program known as Every Woman Counts (EWC). EWC provides free breast and cervical cancer screening and diagnostic services to Californians with incomes at or below 200% FPL and no other coverage (DHCS, 2021).

Existing law requires all individual and group health plans and policies — except for specialized health plans — that include coverage for treatment or surgery of cervical cancer to also provide coverage for an annual cervical cancer screening test, including an HPV screening test that is approved by the FDA.[13]

In 2011, AB 499 was signed by the governor, expanding the legal authority of minors aged 12 or older to consent to confidential medical services for the prevention of sexually transmitted infections (STIs) without parental consent.[14]

California law also authorizes pharmacists who meet certain training and certification requirements to independently administer vaccines that are listed on the routine immunization schedules recommended by the Advisory Committee on Immunization Practices (ACIP) for minors aged 3 or older.[15]

Sources of low- or no-cost HPV vaccines in California

Vaccines for Children (VFC) is a federally funded program that provides no-cost vaccines to eligible children aged 18 years or younger (EZIZ, 2022). To be eligible, children need to be either enrolled in or eligible for Medi-Cal, American Indian or Alaskan Native, uninsured, or underinsured. Enrolled providers order federally funded vaccines through the state VFC program and receive the vaccines at no cost. All vaccines recommended by ACIP (see more information below) are covered, including the HPV vaccine.

[10] For minors aged 17 or younger, parent income is excluded from eligibility determinations (Family PACT, 2022).
[11] California Assembly Bill 1965.
[12] WIC 14132.
[13] HSC 1367.66; INS 10123.18.
[14] FC 6926.
[15] BPC 4052.8

Many pediatrician offices, federally qualified health centers (FQHCs), and community clinics are participating providers.

Individuals aged 19 to 26 years without health insurance and who meet financial criteria may qualify for the Merck Vaccine Patient Assistance Program to receive the HPV vaccine at no charge through Planned Parenthood, although other fees may apply (Planned Parenthood, 2022).

Similar requirements in other states

Hawaii recently introduced legislation similar to AB 2516 that would provide comprehensive coverage for sexual and reproductive health care services, including HPV vaccination. The bill would also prohibit insurers from imposing cost-sharing requirements, with exceptions for high deductible health plans.[16]

Three states and the District of Columbia currently require the HPV vaccine series for school attendance. Washington, D.C., and Virginia both require female students to receive the vaccine before entering 7th grade.[17,18] Rhode Island requires all students to have received at least one dose of the vaccine series before entering 7th grade, at least two doses of the vaccine series before 8th grade, and all three doses before 9th grade.[19] Hawaii requires the vaccine for students entering 7th grade or above.[20]

States have also addressed HPV prevention through other legislative and executive efforts. For example, New Hampshire's Department of Health and Human Services announced in 2006 that the vaccine would be provided with no cost sharing to all females under the age of 18 years (NCSL, 2020).

Currently, every state except New York and New Hampshire allows pharmacists to administer the HPV vaccine. The minimum ages for pharmacist HPV vaccination range from 10 years to 18 years (APhA-NASPA, 2019). New Hampshire introduced legislation this year that would authorize pharmacists to administer the HPV vaccine.[21] New York has also recently introduced legislation that would authorize pharmacists to administer the HPV vaccine.[22] In addition, Hawaii introduced legislation this year that would authorize physician assistants to administer the HPV vaccine to minors aged 11 to 17 years.[23]

New Jersey introduced legislation this year that would permit minors aged 14 and above to consent to certain vaccines, including the HPV vaccine.[24]

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 2516 may interact with requirements of the ACA as presently

[16] Hawaii House Bill 249/Senate Bill 623 of 2021.
[17] D.C. Law 17-10 of 2007.
[18] Virginia House Bill 2035 of 2007.
[19] State of Rhode Island and Providence Plantations Department of Health. Rules and Regulations Pertaining to Immunization and Communicable Disease Testing in Preschool, School, Colleges or Universities [R23-1-IMM]. 2014. Accessed March 24, 2022. Available at: https://risos-apa-production-public.s3.amazonaws.com/DOH/7602.pdf.
[20] Hawaii Administrative Rule 11-147 of 2019.
[21] New Hampshire Senate Bill 229 of 2022.
[22] New York Assembly Bill 3023/Senate Bill 4698 of 2021.
[23] Hawaii House Bill 1575/Senate Bill 2445 of 2022.
[24] New Jersey Assembly Bill 2679 of 2022.

exist in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).[25,26]

Federally Selected Preventive Services

The ACA requires that nongrandfathered group and individual health insurance plans and policies cover certain preventive services without cost sharing when delivered by in-network providers and as soon as 12 months after a recommendation appears from specified entities, including the ACIP recommendations that have been adopted by the Director of the Centers for Disease Control and Prevention (CDC). ACIP currently recommends HPV vaccination at age 11 or 12, although vaccination can begin at the age of 9. Catch-up HPV vaccination is also recommended for all individuals through age 26. For adults aged 27 to 45 years, ACIP recommends shared clinical decision-making for potential HPV vaccination (Meites et al., 2019). Shared clinical decision-making is a discussion between the provider and the patient about the decision whether or not to vaccinate, informed by the best available evidence of who may benefit from vaccination; the individual's characteristics, values, and preferences; the provider's clinical discretion; and the characteristic of the vaccine being considered (CDC, 2020a). In practice, this may include detailed investigation into the enrollee's number of prior sexual partners, including whether they have had any prior sexual exposures at all. The enrollee's potential benefit from HPV vaccination also includes their personal assessment of their own risk of future exposure. The CDC states that the ACA's preventive services requirement includes shared clinical decision-making recommendations when they have been adopted by the CDC and are listed on the immunization schedules. The HPV vaccine is so included (CDC, 2022c).

Essential Health Benefits

In California, non-grandfathered[27] individual and small-group health insurance is generally required to cover essential health benefits (EHBs).[28] In 2023, approximately 12.1% of all Californians will be enrolled in a plan or policy that must cover EHBs. [29]

The HPV vaccine is currently covered by California's EHB benchmark plan and is recommended by ACIP. Therefore, AB 2516 does not exceed the definition of EHBs in California.

Vaccines approved by the U.S. Food and Drug Administration (FDA)

In order to approve vaccines for use in the United States, all vaccines undergo a rigorous review of laboratory and clinical data by the FDA to ensure the safety, efficacy, purity, and potency of the vaccine (FDA, 2021). The FDA has approved three HPV vaccines for use in the United States (FDA, 2022). Gardasil® has been approved for use in females and males aged 9 to 26 years, Gardasil® 9 has been approved for use in females and males aged 9 to 45 years, and Cervarix™ has been approved for use in females aged 9 to 25 years. Gardasil® 9 is currently the predominant vaccine on the market in the U.S. (Cervarix™ is no longer sold in the United States). More information about these vaccines and the strains of HPV against which they protect is included in the *Background* section.

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[25] 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.
[26] 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.
[27] A grandfathered health plan is "a group health plan that was created — or an individual health insurance policy that was purchased — on or before March 23, 2010. Plans or policies may lose their 'grandfathered' status if they make certain significant changes that reduce benefits or increase costs to consumers." (HealthCare.gov, 2022)
[28] For more detail, see CHBRP's issue brief, *California State Benefit Mandates and the Affordable Care Act's Essential Health Benefits*, available at https://chbrp.org/other_publications/index.php.
[29] See CHBRP's resource *Estimates of Sources of Health Insurance in California* and CHBRP's issue brief *California State Benefit Mandates and the Affordable Care Act's Essential Health Benefits: An Update and Overview of New Federal Regulations*, both available at https://chbrp.org/other_publications/index.php.

Cost Sharing

Payment for use of covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Common cost-sharing mechanisms include copayments, coinsurance, and/or deductibles (but do not include premium expenses[30]). Some health insurance benefit designs incorporate higher enrollee cost sharing in order to lower premiums. Reductions in allowed copayments, coinsurance, and/or deductibles can shift the cost to premium expenses or to higher cost sharing for other covered benefits.[31]

To be eligible to establish a Health Savings Account (HSA) for taxable years beginning after December 31, 2003,[32] (and so to be eligible to make tax-favored contributions to an HSA), a person must be enrolled in an HSA-qualified high deductible health plan (HDHP). In order for an HDHP to be HSA qualified, it must follow specified rules regarding cost sharing and deductibles, as set by the IRS. Generally, an HDHP may not provide benefits for any year until the deductible for that year is satisfied, but federal law provides a safe harbor for the absence of a deductible applicable to preventive care.[33] Therefore, an HDHP may cover preventive care benefits without any deductible or with a deductible below the minimum annual deductible, but is not required to do so for a specified list of preventive services. Child and adult immunizations are listed as preventive services, and therefore, the requirements of AB 2516 would not interfere with an HDHP's qualification for an HSA.

Summary of Key Policy Changes Due to AB 2516

The HPV vaccine is currently approved by the FDA for persons aged 9 to 45, while ACIP recommends the HPV vaccine for persons aged 9 to 26 and recommends shared clinical decision-making for persons aged 27 to 45. Nongrandfathered plans and policies are required to cover the HPV vaccine as recommended by ACIP without cost sharing. AB 2516 would expand the requirement to all DMHC-regulated plans and CDI-regulated policies, including those with grandfathered status.

AB 2516 would require Family PACT to provide the HPV vaccine as a covered benefit, for persons for whom the FDA has approved the vaccine (females and males aged 9 to 45 years). Governor Newsom's 2022–2023 draft budget provides a funding allocation to provide coverage of the HPV vaccines for persons ages 19 to 45 years. This is because persons in California younger than 19 years who are eligible for Family PACT are usually eligible for other types of publicly funded insurance coverage or have access to no-cost vaccinations, either through Medi-Cal or through VFC.

CHBRP makes the following assumptions for this analysis:

- CHBRP assumes plans and policies would still be able to have prior authorization requirements for provision of the HPV vaccine postmandate. For some enrollees, this may continue to pose a barrier to accessing the HPV vaccine, even with coverage without cost sharing.

[30] Premiums are paid by most enrollees, regardless of their use any tests, treatments, or services. Some enrollees may not pay premiums because their employers cover the full premium, they receive premium subsidies through the Covered California, or they receive benefits through Medi-Cal.

[31] Plans and policies sold within Covered California are required by federal law to meet specified actuarial values. The actuarial value is required to fall within specified ranges and dictates the average percent of health care costs a plan or policy covers. If a required reduction in cost sharing impacts the actuarial value, some number of these plans or policies might have to alter other cost-sharing components of the plan and/or premiums in order to keep the overall benefit design within the required actuarial value limits.

[32] Section 1201 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, added section 223 to the Internal Revenue Code

[33] For more information on screening services, see Notice 2004-23, 2004-15 I.R.B. 725, available at IRS.gov/irb/2004-15_IRB#NOT-2004-23.
For additional guidance on preventive care, see Notice 2004-50, 2004-2 C.B. 196, Q&A 26 and 27, available at IRS.gov/irb/2004-33_IRB#NOT-2004-50; and Notice 2013-57, 2013-40 I.R.B. 293, available at IRS.gov/pub/irs-drop/n-13-57.pdf.

BACKGROUND ON HPV VACCINATION

Human papillomavirus (HPV) is a group of more than 200 viruses, 14 of which have been identified as high risk, and are associated with several types of cancers, including nearly all cervical cancers, and most anal, vaginal, penile, vulvar, head, and neck cancers (NCI, 2021). Depending on the type of HPV and the immune system of the individual, infection can cause no symptoms at all and completely resolve, lead to the development of genital warts, or persist and potentially develop into precancerous cell changes or cancer in later life (CDC, 2021c).

In 2006, the FDA approved the first HPV vaccine, Gardasil®, for use in females aged 9 to 26 years. It was developed to protect against four strains of HPV — 6, 11, 16, and 18 — that can cause genital warts; precancerous changes in the cervix; and cervical, anal, vulvar, and vaginal cancers (FDA, 2018). In 2009, the Gardasil® vaccine expanded its approval for use in males aged 9 to 26 years (CDC, 2010). In 2009, another vaccine, Cervarix™, was also approved by the FDA for protection against HPV types 16 and 18 (FDA, 2019). Though it is approved for clinical use, sales of Ceravix™ within the United States stopped in 2016 (Mulcahy, 2016). Much of the research on the effectiveness of the HPV vaccines over time is based on people who received these earlier vaccines. Gardasil® 9 was developed to provide additional protection from even more strains. In 2018 the FDA approved Gardasil® 9 for both males and females, aged 9 to 45 years (FDA, 2020). The indications for the vaccine now include prevention of certain head, neck, and anal cancers. Gardasil® 9 protects against 9 subtypes of HPV: 6, 11, 16, 18, 31, 33, 45, 52, and 58. Types 6 and 11 cause genital warts but not cancer. Persistent infection with the remaining types can cause precancerous changes of the cervix, cervical cancer, and other various cancers listed in Table 2. At this time, Gardasil® 9 is the predominant vaccine on the market in the United States.

Table 2. Prevalence of HPV-Related Health Conditions in the United States, 2006/2017

HPV Subtypes	Condition (Percentage of Cases Due to HPV Subtype)	Health Burden in the General Population
HPV 6 and 11 (a)	Genital warts (90%)	Estimated prevalence of 10%–20%
HPV 16 and 18 (b) (c) (d)	Cervical cancer (70%)	Annual incidence: 7.5 per 100,000
	Head and neck (Oropharyngeal) cancers (70%)	Annual incidence: 2.8 per 100,000
	Anal cancer (90%)	Annual incidence: 1.9 per 100,000
	Penile cancer (60%)	Annual incidence: <1 per 100,000
	Vaginal cancer (75%)	Annual incidence: <1 per 100,000
	Vulvar cancer (70%)	Annual incidence: 2.5 per 100,000
HPV 31, 33, 45, 52, and 58 (a)	Cervical cancer (10-20%)	Annual incidence: 7.5 per 100,000

Source: California Health Benefits Review Program, 2022.

Notes: (a) Leslie et al., 2022.

(b) Chan et al., 2019.

(c) NCI, 2021.

(d) Barnholtz-Sloan et al., 2007.

HPV Infections and Development of Cancers

HPV is usually spread through sexual activity with an infected partner (NCI, 2021). It is the most common sexually transmitted infection in the United States with an estimated 13 million new cases each year and will infect approximately 85% of the population at some point in their lifetime (CDC, 2021c; 2021d). Most

people have been infected with HPV by age 27, and for this reason the vaccine is recommended primarily for those aged 11 to 12 by the Advisory Committee on Immunization Practices (ACIP) as the vaccine is most effective for individuals who have not yet been exposed to the virus (often occurring soon after initiating sexual activity) (CDC, 2022b).

Because HPV infection most often occurs and resolves without symptoms, medical treatment is typically unnecessary. Treatment is available, however, for genital warts caused by HPV 6 and/or HPV 11. Treatment options include topical ointments, cryotherapy, or surgical removal (CDC, 2021a). Genital warts can also be left alone and wait to see if they resolve on their own (CDC, 2021a).

Infection with high-risk strains of HPV can persist without symptoms and develop over time into precancerous cervical lesions, invasive cervical cancer, and other types of cancer, depending on the site of infection. Precancerous cervical lesions caused by HPV infection are often initially detected by the Pap test. Abnormalities of cervical cells may indicate the presence of cervical intraepithelial neoplasia (CIN), which is confirmed with a cervical biopsy and graded 1, 2, or 3, indicating progressive severity of the abnormalities. CIN 1 is common and relatively benign, often resolving spontaneously. CIN 2 and CIN 3 represent increasing levels of abnormality and may ultimately progress to cervical cancer. CIN 3 and adenocarcinoma in situ are the most important precursors of invasive cervical cancer. Precancerous changes of the cervix found on screening may be treated with cryotherapy, laser treatment, or surgery. However, not all CIN 2 and CIN 3 lesions progress to cancer: up to 40% of CIN 2 lesions will regress over two years (Castle et al., 2009). When cervical cancer develops, the progression from initial infection to cancer takes approximately two decades on average (ACS, 2022).

Because CIN 2 and, especially, CIN 3 are considered precancerous lesions occurring early in the course of infection, they are useful markers of the level of protection afforded by HPV vaccines. Documenting prevention of CIN 2 and CIN 3 provide some evidence of protection against later cervical cancer, because it represents an interruption of the path of development toward cancer. Reduction of cervical cancer in vaccinated individuals is the ultimate health outcome. Although evidence is emerging in Sweden that HPV vaccination is contributing towards a decline in cervical cancer incidence (Lei, Ploner et al. 2020), evidence of such an effect in other countries may not be available for several decades, given the time required for such cancers to develop.

HPV is the leading cause of cervical cancer, which is diagnosed in about 12,200 females per year in the United States and was the cause of death for approximately 4,290 females in 2021 (CDC, 2021b; NCI, 2022a). In 2018, 469 females in California died from cervical cancer (CCR, 2018). Cervical cancer can be avoided when precancerous lesions are treated early; the USPSTF recommends screening every 3 to 5 years for females aged 21 to 65 years (USPSTF, 2018). Cervical cancer can take 5 to 20 years to develop and may require surgery, radiotherapy, and/or chemotherapy to treat (WHO, 2022a). HPV is also the cause for approximately 863 vaginal, 4,191 vulval, 4,909 anal, and 3,556 cancers of the head and neck in the United States each year (CDC, 2021b).

For males, HPV is the cause for approximately 1,365 penile, 2,379 anal, and 16,680 cancers of the head and neck (oropharynx) in the United States each year (CDC, 2021b).

ACIP notes that the HPV vaccine is most effective for patients who have not yet been exposed to the virus (often occurring soon after initiating sexual activity) (Meites et al., 2019). As such, ACIP recommends that adolescents remain the primary focus for HPV vaccination. For dosage, ACIP recommends that children aged 9 to 14 years receive two doses of the HPV vaccine, whereas persons aged 15 to 45 years and those who are immunocompromised, should receive 3 doses (Meites et al., 2016). ACIP recommends all people aged 9 to 26 years receive the HPV vaccine, and for those older than 26, they advise shared decision-making between the physician and patient. In California, approximately 62.3% of adolescents aged 13 to 17 years have received all recommended doses of the HPV vaccine (UHF, 2021). This is slightly above the national average of 58.6%. Differences in both initiation and completion of the recommended HPV vaccine series exist by race, ethnicity, and sex (Table 3).

Table 3. National HPV Vaccination Coverage Among Adolescents Aged 13–17 Years by Race/Ethnicity, 2020

	White	Black	Hispanic	American Indian/Alaska Native	Asian	Multiracial, non-Hispanic
All Adolescents						
At Least Partially Vaccinated	71.1%	78.1%	80.0%	85.3%	77.2%	77.9%
Fully Vaccinated	55.4%	60.7%	62.7%	66.4%	60.9%	60.7%
Females						
At Least Partially Vaccinated	72.4%	80.0%	84.0%	91.8%	77.0%	79.3%
Fully Vaccinated	57.1%	63.9%	67.9%	71.8%	62.6%	62.8%
Males						
Partially Vaccinated	69.9%	76.1%	76.5%	77.1%	77.4%	76.3%
Fully Vaccinated	53.8%	57.4%	58.3%	59.5%	59.2%	58.2%

Source: California Health Benefits Review Program, 2022.

Note: Data obtained from CDC, 2021e.

There is limited data available to determine HPV vaccination rates among adults; however, it is likely lower. One study used data from the 2018 National Health Interview Survey and estimated that approximately 55% of females and 34% of males aged 18 to 21 years had received at least one dose of the HPV vaccine (Chen et al., 2021). Of those who had the HPV vaccine, only 4% of females, and 3% of males received their first dose between the ages of 18 and 21 years (Chen et al., 2021).

Since introduction of the HPV vaccine in 2006, HPV infections associated with genital warts and most HPV-related cancers have dropped 88% among adolescent females, and 81% among adult females, and cervical precancerous changes have decreased 40% among adult females (CDC, 2021c). Table 4 describes the change in incidence of cervical cancer by race/ethnicity in California and the United States since the introduction of the HPV vaccine; however, increased screening and early detection may have also contributed towards the decline.

Table 4. Cervical Cancer Incidence Rates per 100,000 Females by Race/Ethnicity, 2017/2018 and 2006

Year	Overall	Asian or Pacific Islander	White	Black	Hispanic
California (a)					
2006	8.1	7.7	8.4	6.5	9.0
2017	7.2	7.4	7.5	5.9	7.5
National (b)					
2006	8.1	7.8	7.1	10.3	12.3
2018	7.5	6.1	6.7	8.9	9.6

Source: California Health Benefits Review Program, 2022.

Notes: (a) KFF, 2022.

(b) NCI, 2022a.

Disparities[34] and Social Determinants of Health[35] in Use of the HPV Vaccine

Per statute, CHBRP includes discussion of disparities and social determinants of health (SDOH) as it relates to the HPV vaccine. Disparities are noticeable and preventable differences between groups of people. CHBRP found literature identifying disparities by gender, gender identity, sexual orientation, and race.

Disparities

Race or ethnicity

Some U.S. studies have demonstrated that Black, Hispanic, and "Other" racial/ethnic groups were 5% to 7% less likely to receive a recommendation from their doctor to receive the HPV vaccine (Kong et al., 2021). Despite this, additional studies found that Hispanic, Black, and Asian adolescents are more likely to initiate the HPV vaccine series than White adolescents but were less likely to complete the full series (Spencer et al., 2019). This disparity in completion of the full series is demonstrated in national HPV vaccination coverage rates, shown previously in Table 3. However, downstream effects of the HPV vaccine's impact on national cervical cancer incidence and mortality will take many years to manifest, and are yet to be fully realized, as demonstrated by the disparities shown in Table 5 below.

[34] 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).

[35] 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; Office of Disease Prevention and Health Promotion, 2019).

Table 5. California Cervical Cancer Incidence and Mortality Rates by Race/Ethnicity, 2018

Race/Ethnicity	Incidence (per 100,000)	Mortality (per 100,000)	Percent Survival
Asian/Pacific Islander	5.7	2.0	65.2%
Non-Hispanic Black	6.7	2.7	52.8%
Hispanic	9.5	2.7	66.1%
Non-Hispanic White	6.6	1.7	66.5%

Source: California Health Benefits Review Program, 2022.

Note: Data obtained from CCR, 2018.

Sex or gender[36]

Initial iterations of the HPV vaccine were indicated for females only, due to its limited aim towards preventing cervical cancer. Since then, the HPV vaccine has been recognized to have potential to prevent certain anal, head, and neck cancers. As such, it is now indicated to be received by all genders. However, studies have demonstrated that males are less likely to receive a recommendation for the HPV vaccine from their doctor (Kong et al., 2021).

Gender identity or sexual orientation[37]

Limited research is available for HPV vaccination rates among the LGBTQIA community. However, one observational study of gay men, bisexual men, and transgender women aged 18 to 26 years living in the Los Angeles area found that only 26.3% of participants had received at least one dose of the HPV vaccine (Amiling et al., 2021). This was the lowest rate of all sites participating in the study (Seattle: 36.6%; Chicago: 37.1%).

Social Determinants of Health

SDOH include factors outside of the traditional medical care system that influence health status and health outcomes (e.g., income, education, geography). CHBRP found literature that indicates differences in the likelihood of obtaining the HPV vaccine based on where people live, and what type of insurance they have.

In 2018, adults aged 18 to 26 years living in rural areas were less likely to have received the HPV vaccine than those living in urban areas (Song et al., 2021; Walker et al., 2019). They were also less likely to have received the HPV vaccine if they had lower incomes, and/or did not have health insurance (Kong et al., 2021; Song et al., 2021). Another study showed that for teens aged 13 to 17 years with health insurance, those covered under Medicaid were significantly more likely to have received at least one dose of the HPV vaccine than those with private health insurance (Lu et al., 2018). Passage of the Affordable Care

[36] CHBRP uses the National Institutes of Health (NIH) distinction between "sex" and "gender:" "'Sex' refers to biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles. 'Gender' refers to socially constructed and enacted roles and behaviors which occur in a historical and cultural context and vary across societies and over time." (NIH, 2019).

[37] CHBRP defines gender identity as one's internal sense of one's own gender, or the gender in which a person identifies, whether it be male, female, or nonbinary. Gender identity and sexual orientation are different facets of one's identity; an individual's gender does not determine a person's sexual orientation (i.e., a person's emotional, romantic, or sexual attraction to other people) (ACOG, 2020; CDC, 2017).

Act eliminated cost sharing for vaccines recommended by ACIP for public and most private health insurance plans, which contributed to an increase in HPV vaccination rates (Hawkins et al., 2021).

Societal Impact of HPV in California

The presence of HPV infection in the United States has direct and indirect economic and societal costs (Chesson et al., 2019). Treatment for cervical cancers caused by HPV costs approximately $1.2 billion per year, and treatment of anal cancers about $1.1 billion per year in the United States (Lairson et al., 2017; Wu et al., 2018). Note that the societal impact discussed here is relevant to a broader population than AB 2516 impacts, which would affect the health insurance of a subset of Californians (see *Policy Context* section). See the *Benefit Coverage, Utilization, and Cost Impacts* section for estimates of direct cost impacts for the specific population targeted by AB 2516.

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, AB 2516 would require coverage without cost sharing of the human papillomavirus (HPV) vaccine for persons for whom the vaccine is approved by the U.S. Food and Drug Administration (FDA). The medical effectiveness review summarizes findings from evidence[38] on the clinical effectiveness of the HPV vaccine for males and females.

Research Approach and Methods

Studies of the clinical effectiveness of the HPV vaccine were identified through searches of PubMed, the Cochrane Library, Web of Science, and the Cumulative Index of Nursing and Allied Health Literature (CINAHL). Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the 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.

The search was limited to studies published from 2012 to present. CHBRP relied on three systematic reviews (Arbyn et al., 2018; Drolet et al., 2019; Kurosawa et al., 2022) for the majority of the research findings. Of the 419 articles found in the literature review, 52 were reviewed for potential inclusion and a total of 28 studies were included in the medical effectiveness review for this report. The other articles were eliminated because they did not focus on the key questions noted below, were of poor quality, or did not report findings from clinical research studies. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.[39] 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 is the clinical effectiveness of HPV vaccination for preventing HPV-related precancerous changes of the cervix and cervical cancers in females?
2. What is the clinical effectiveness of HPV vaccination for preventing other HPV-related cancers in females and males?
3. What is the clinical effectiveness of HPV vaccination for preventing HPV-related genital warts for females and males?

This report examines the clinical effectiveness of the HPV vaccinations by age, specifically the 9- to 26-year-old population and the 27- to 45-year-old population.

[38] 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.

[39] 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.

Methodological Considerations and Outcomes Assessed

Given the relatively low incidence and the long time to progression (>10 years) for the HPV-associated cancers developing from the epithelium, the World Health Organization expert consensus is that trial investigators should use incident high-grade proliferative lesions (for example, high-grade cervical intraepithelial neoplasia [CIN] and adenocarcinomas in situ) as the clinical end points of HPV vaccine trials. The key outcomes for evaluating the effectiveness of vaccination are the effect of vaccination on overall HPV-related genital warts, and, most importantly, the overall incidence of precancerous changes and cancers in vaccinated individuals compared to unvaccinated individuals. Many studies of HPV vaccination report on viral type-specific HPV infection and type-specific precancerous changes on the cervix. These are intermediate outcomes that do not provide conclusive evidence of effectiveness.

CHBRP focused on trials and systematic reviews that reported these intermediate outcomes in this review. Studies reviewed in this report address the evidence on the effectiveness of HPV vaccination for reductions in CIN 2 and CIN 3 lesions[40] (representing an interruption of the pathway toward cervical cancer), adenocarcinoma in situ (AIS), vaginal intraepithelial neoplasia (VAIN), vulvar intraepithelial neoplasia (VIN), anal cancers (AIN), oral or oropharyngeal cancers and anogenital warts.

Study Findings

CHBRP categorized study findings loosely in alignment with ACIP's age-based recommendations for the HPV vaccine: persons vaccinated between ages 9 and 26, and persons vaccinated between ages 27 and 45. However, many of the studies include age rages that do not align with ACIP's division. Many studies have age rages that are lower than age 26 or span the two categories (i.e., persons vaccinated between ages 24 and 30). The section headers and summary statements refer to ACIP's age classifications, while the text describing the studies mentions the specific ages included in the study.

The following section summarizes CHBRP's findings regarding the strength of evidence for the effectiveness of the HPV vaccine to prevent genital warts, precancerous changes of the cervix and cervical cancer, and other cancers and precancerous changes.[41] For females vaccinated at age 26 or younger and who are HPV negative at the time of vaccination, CHBRP found *clear and convincing evidence* that the HPV vaccine is effective against cervical cancer, high-grade CIN, AIS, and genital warts. For older females, the evidence is *limited* that the HPV vaccine is effective against high-grade CIN and AIS. There is *insufficient evidence* that HPV vaccines reduce the overall incidence of AIN, or oral or oropharyngeal cancers after vaccination at any age. There is *a preponderance of evidence* that the HPV vaccine is effective at providing protection against HPV-related anogenital disease in males vaccinated at age 26 or younger. There is *clear and convincing evidence* that the HPV vaccines prevent HPV-related anogenital warts for females and males vaccinated at age 26 or younger.

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.

[40] Cervical intraepithelial neoplasia (CIN): Abnormal cells are found on the surface of the cervix. CIN is usually caused by certain types of human papillomavirus (HPV) and is found when a cervical biopsy is done. CIN is not cancer, but may become cancer and spread to nearby normal tissue. It is graded on a scale of 1 to 3, based on how abnormal the cells look under a microscope and how much of the cervical tissue is affected (National Cancer Institute, 2022).

[41] More than 200 types of HPV have been identified, which are classified into high-risk types (such as types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68, 73, and 82) that are carcinogenic, and low-risk types (such as types 6, 11, 42, 43, and 44) that cause anogenital warts and benign tumors, such as condyloma acuminata (Kurosawa et al., 2022).

CHBRP relied on three systematic reviews (Arbyn et al., 2018; Drolet et al., 2019; Kurosawa et al., 2022) for findings from studies published prior to 2018:

- Arbyn et al. (2018) included 26 randomized trials on vaccine efficacy and/or safety, which together enrolled 73,428 women. One study evaluated efficacy of a monovalent HPV 16 vaccine, 18 trials evaluated the bivalent vaccine, and seven others evaluated the quadrivalent vaccine.[42] Ten trials, with follow-up of 1.3 to 8 years, addressed protection against CIN and AIS. The duration of follow-up post-vaccination in the studies was too short to show effects on cervical cancer outcomes; rather, results focused on efficacy of protection against precancerous cervical lesions and of HPV 16/18 infection. All but one of the trials was funded by the vaccine manufacturers. While most females were under 26 years of age, three trials recruited females aged 25 and over. The results in this report refer to findings for participants who had at least one dose of the HPV vaccine.

- Drolet et al. (2019) assessed the relative risk (RR) of genital HPV, infections, anogenital wart diagnoses, or histologically confirmed CIN 2+ by comparing the frequency (prevalence or incidence) of HPV-related endpoints between the pre-vaccination and post-vaccination periods in a systematic review/meta-analysis of 65 studies.

- Kurosawa et al. (2022) reported the long-term effectiveness of HPV vaccination from a review of 32 randomized controlled trials (RCTs) and four observational studies with observation periods for the bivalent vaccine up to 12 years, 8 years for the 9-valent vaccine, and 14 years for the quadrivalent vaccine on genital warts, cervical and/or genital pre-cancers, or cancers.

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.

[42] Three prophylactic HPV vaccines are licensed for use in the United States: 9-valent (9vHPV, Gardasil 9, Merck), quadrivalent (4vHPV, Gardasil, Merck), and bivalent (2vHPV, Cervarix, GlaxoSmithKline). Only 9vHPV is distributed in the United States since 2016. The majority of HPV-associated cancers are caused by HPV 16 or 18, types targeted by all three vaccines. In addition, 4vHPV and 9vHPV target HPV 6 and 11, viral types that cause anogenital warts but not cancer. 9vHPV also protects against five additional high-risk types: HPV 31, 33, 45, 52, and 58.

Findings on the Clinical Effectiveness of the HPV Vaccine for Preventing HPV Infection-Related Outcomes in Females Vaccinated at Age 26 or Younger

High-risk HPV negative at baseline who received at least one dose of vaccine

Arbyn et al. (2018) reported that at 3 to 5 years follow-up, for females aged 15 to 26 years at time of vaccination and negative at baseline for any high-risk HPV, the HPV vaccine significantly reduced the risk of cervical precancers regardless of HPV type or bivalent or quadrivalent vaccine from 287 to 106/10,000 females for any HPV-associated CIN 2+ (5 RCTs; n=25,180; RR 0.37) and from 109 to 23/10,000 females for any HPV-associated CIN 3+(3 RCTs; n= 20,719; RR 0.21) with at least one vaccine dose (Arbyn et al., 2018; 26 trials; 73,428 participants).

HPV 16/18 negative at baseline who received at least one dose of vaccine

Arbyn et al. (2018) reported that for females aged 15 to 26 years at time of vaccination who were HPV 16/18 negative at baseline, vaccines reduced any HPV-associated CIN 2+ from 231 to 95/10,000 females (2 RCTs; 19,143 participants; RR 0.41) with an efficacy rate[43] of 58%; reduced the risk of CIN 3+ from 57 to 3/10,000 females with a 95% efficacy rate (3 RCTs; 33,199 participants; RR 0.05); and reduced AIS from 12 to 0/10,000 females with a vaccine efficacy of 81% (2 RCTs; 17,079 participants).

HPV vaccine for females regardless of HPV status at baseline who received at least one dose of vaccine

At follow-up of 3.5 to 8.5 years, HPV vaccines reduce CIN 2+ associated with any HPV from 559 to 391/10,000 females (RR 0.70) and AIS associated with any HPV from 17 to 5/10,000 females (RR 0.32) (Arbyn et al., 2018).

Long-term effect (precancerous changes)

Kurosawa et al. (2022) reviewed six studies that reported significant protection against HPV-related infections or pathological abnormalities against precancerous changes for up to 14 years follow-up (Huh et al., 2017; Kjaer et al., 2020; Kjaer et al., 2021b; Naud et al., 2014; Olsson et al., 2020; Ruiz-Sternberg et al., 2018).

Long-term effect (cervical cancer)

Kurosawa et al. (2022) reviewed two studies that reported significant protection against HPV-related infections or precancerous changes of the cervix (CIN 2+ or 3+) on long-term follow-up studies using birth cohorts. One study (Machalek et al., 2018) found significantly reduced high-risk HPV prevalence between vaccinated and pre-vaccinated generations. Another study (Thamsborg et al., 2020; 19,951 subjects) comparing birth cohorts found that women born in the cohort with a 91% vaccination rate showed a significantly lower relative risk of developing CIN 2+ (RR = 0.74) and CIN 3+ (RR 0.68) compared to women born in a cohort with <0.1% vaccination rate. In a metanalysis, Drolet et al. (2019) reported that 3 years after vaccination, CIN 2+ decreased significantly among women aged 20 to 24 years.

Four recent observational cohort studies have shown significant reduction in the incidence of cervical cancer in vaccinated compared to unvaccinated populations.

A clustered randomized cohort follow-up analysis of the Papilloma Trial against Cancer in Young Adults (PATRICIA), 012 trial, and Females United to Unilaterally Reduce Endo/Ectocervical Disease (FUTURE)

[43] A vaccine's efficacy is measured in a controlled clinical trial and is based on how many people who got vaccinated developed the 'outcome of interest' (usually disease) compared with how many people who got the placebo (dummy vaccine) developed the same outcome (WHO, 2022b).

II (3,341 participants, 16,526 non–HPV-vaccinated controls) reported significant difference in cervical cancer incidence rates for HPV-vaccinated females versus HPV-unvaccinated females (0.0 vs. 9.8; 95% CI, 6.1–15.7) and 100% HPV-vaccine efficacy against all HPV DNA-positive invasive cervical cancers (14/17 cancers were cervical cancers) 11 years after the clinical trials ended (up to 17 years post-vaccination) (Lehtinen et al., 2021).

A registry-based cohort study (Lei et al., 2022; 1,672,983 participants) from the Swedish Total Population Register comparing crude incidence rates among unvaccinated and vaccinated (before age 20) females in Sweden from 2006 until their 31st birthday found significant reductions in the crude incidence of cervical cancer rates among females vaccinated before age 20 compared to unvaccinated females (0.10 per 100,000 person-years compared to 5.27 per 100,000 person-years). After adjusting for age, year, and residential and parental characteristics, the incident rate ratio (IRR) was 0.12 (95% CI, 0.00–0.34) among females vaccinated before age 17. For women vaccinated before age 20, the crude incidence of cervical cancer was 0.49 (95% CI, 0.28–5.73) per 100,000 person-years. After adjusting for age, year and residential and parental characteristics, the IRR of cervical cancer was 0.36 (95% CI, 0.18–0.61) among women who had been vaccinated before age 20.

Another observational cohort study of women aged 20 to 30 years at follow-up reported that the estimated relative reduction in cervical cancer rates were 34% (95% CI, 25–41) among females vaccinated between the ages of 16 and 18 years, 62% (95% CI, 52–71) when vaccinated between the ages of 14 and 16 years, and 87% (95% CI, 72–94) when vaccinated at age 12 or 13 years, compared with the reference unvaccinated cohort (Falcaro et al., 2021;13.7 million person-years). Another observational cohort study reported reduced IRRs for cervical cancer in females vaccinated at age 16 years or younger (0.14; 95% CI, 0.04–0.53) and between ages 17 to 19 years (0.32; 95% CI, 0.08–1.28) compared with unvaccinated women (Kjaer et al., 2021a; 867,689 participants).

The Swedish cohort study (Lei et al., 2020; 1,672,983 participants) also compared crude incidence rate among unvaccinated and vaccinated females aged 17 to 30 years at time of vaccination from 2006 until their 31st birthday. The researchers found reductions in cervical cancer rates among females vaccinated between the ages of 17 and 30 years compared to unvaccinated females. The incidence of cervical cancer among females vaccinated between the ages of 17 and 30 years was 3.02 (95% CI, 1.88–4.86) per 100,000 person-years. For women aged 20 to 30 years, the crude incidence rate of cervical cancer was similar to the unvaccinated population: 5.16 (95% CI, 2.46–10.83) per 100,000 person-years versus 5.27 (95% CI, 4.84–5.73) per 100,000 person-years in the unvaccinated population. After adjusting for age, year, and residential and parental characteristics, the fully adjusted IRR of cervical cancer among women who had been vaccinated between the ages of 17 and 30 years was 0.47 (95% CI, 0.27–0.75) and 0.38 (95% CI, 0.12–0.72) among women who had been vaccinated between the ages of 20 and 30 years.

Summary of findings regarding the clinical effectiveness of the HPV vaccine for the prevention of cervical lesions in females vaccinated at age 26 or younger: CHBRP found *clear and convincing evidence* that the HPV vaccine is effective against developing high-grade CIN and AIS, based on two large systematic reviews (Arbyn: 26 trials; Kurosawa: 36 studies). As these outcomes are precursors to cervical cancer, there is strong support of the effect of the vaccine on reducing cervical cancer. Long-term follow-up from four studies showed a significant difference in cervical cancer. There is substantial data that supports the preventive effect of HPV vaccines against cervical cancer in both clinical trials and real-world data. Therefore, CHBRP found *clear and convincing evidence* that the HPV vaccine is effective against developing cervical cancer in females vaccinated before age 27.

Figure 1. Clinical Effectiveness of the HPV Vaccine for the Prevention of Cervical Lesions in Females Vaccinated at Age 26 or Younger

Findings on the Clinical Effectiveness of the HPV Vaccine for the Prevention of Cervical Lesions in Women Vaccinated at Age 27 or older

High-risk HPV negative at baseline

As noted in the *Background* section, most people are infected with HPV through sexual activity, though only some are infected with high-risk HPV strains. There was no data that compared HPV vaccines with placebo for women who received that vaccine over age 26 that were HPV negative at baseline for the reduction of CIN 2+, CIN 3+, or AIS associated with any HPV strains.

HPV 16/18 negative at baseline

Arbyn et al. (2018) reported that, for women negative for HPV 16/18 and aged 24 to 45 years at time of vaccination, HPV vaccines significantly reduced CIN 2+ from 45 to 14/10,000 women and demonstrated a vaccine efficacy rate of 70% at 4 to 6 years follow-up (2 RCTs; n=7552; RR 0.30). No trials of women vaccinated after age 26 years have measured the risk reduction of the HPV vaccines on CIN 3+ and AIS.

Regardless of HPV DNA status

Arbyn et al. (2018) reported that for women aged 24 to 45 years at time of vaccination without regard to HPV 16/18 status, there was no significant change in the risk of CIN 2+ for women following HPV vaccination. The risks of CIN 2+ associated with any HPV type were similar between vaccinated and unvaccinated women (342 vs. 356 per 10,000 women; 2 RCTs; n= 9287). No data are reported in this age group for CIN 3+ or AIS.

The Kurosawa et al. (2022) systematic review reported on three RCTs that demonstrated reduction of specific types of HPV infection in women vaccinated after age 24, but no reduction in overall precancerous changes or cervical cancer was identified. This review reported that two population-level studies reported significantly lower rates of HPV infection rates in women vaccinated between the ages of 18 and 35 years, 9 to 12 years after vaccine program introduction. Another systematic review (Drolet et al., 2019) also reported that, among women vaccinated between the ages of 25 and 29 years, the prevalence of HPV infection did not significantly change in the first 4 years after vaccination, whereas after 5 to 8 years there was a significant decrease in prevalence of HPV infections.

Summary of findings regarding on the clinical effectiveness of the HPV vaccine for the prevention of cervical lesions in women vaccinated at age 27 or older: There is *limited evidence* that the HPV vaccine is effective based on three systematic reviews, notably for lesions caused by HPV 16/18. There are no studies for women vaccinated after age 24 years who are negative for all high-risk HPV strains at baseline on CIN 2+, CIN 3+, and AIS associated with any high-risk HPV strains. For women negative for HPV 16/18 (but potentially positive for other strains) and vaccinated between ages 24 and 45, HPV vaccines significantly reduced CIN 2+. For studies that do not consider HPV status at baseline, the risks of CIN 2+ associated with any HPV type are similar between vaccinated and unvaccinated women.

Figure 2. Clinical Effectiveness of the HPV Vaccine for the Prevention of Cervical Lesions in Women Vaccinated at Age 27 or older

Findings on the Clinical Effectiveness of the HPV Vaccine for the Prevention of Oral or Oropharyngeal HPV-Related Oral Infections, Precancers, and Cancers in Females and Males

One systematic review of males and females vaccinated between the ages of 9 and 45 years reported a decrease in vaccine-type oral or oropharyngeal HPV infections in study participants immunized with HPV vaccines (mean relative prevention percentage [RPP] from cross-sectional studies: 83.9%; 1 RCT: 82.4%; 1 longitudinal cohort study: 83%) (Nielsen et al., 2021; 9 studies; 48,777 participants). Villa et al. (2020) reported that no reviews exist with data regarding the direct effect of HPV vaccines on oral or oropharyngeal precancerous lesions or cancers.

Summary of findings regarding the clinical effectiveness of the HPV vaccine for the prevention of oral or oropharyngeal HPV infections, precancers, and cancers in females and males vaccinated up to age 45: There is *limited evidence* that the HPV vaccine is effective based on nine studies for the prevention of oral or oropharyngeal HPV infections. While studies show a decrease in vaccine-type oral or oropharyngeal HPV infections in study participants, and many cancers are related to persistent high-risk HPV infection, no studies identified reported the overall incidence on the clinically meaningful outcomes of oral or oropharyngeal precancerous lesions or cancers after vaccination. Therefore, there is *insufficient evidence* of the impact of HPV vaccines on oral or oropharyngeal cancers.

Figure 3. Clinical Effectiveness of the HPV Vaccine for the Prevention of Oral or Oropharyngeal HPV Infections in Females/Males Vaccinated at Any Age

Findings on the Clinical Effectiveness of the HPV Vaccine for the Prevention of Anal Intraepithelial Neoplasia (AIN)/Cancer in Males Vaccinated Between the Ages of 9 and 76 Years

HPV vaccine for males

Two RCTs in males report protection by the HPV vaccine against anogenital disease related to HPV 6, 11, 16, and 18 (Harder et al., 2018; Goldstone et al., 2022; Olsson et al., 2020). With a median of 9.5 years follow-up after third vaccine dose in men who have sex with men (MSM) vaccinated between the ages of 16 and 23 years, the incidence of AIN or anal cancer was 20.5/10,000 versus 906.2/10,000 for men compared to placebo (Goldstone et al., 2022). Olsson reported that at approximately 8 years after vaccination, for males vaccinated between the ages of 9 and 15 years, no cases of HPV-related high-grade intraepithelial neoplasia or penile intraepithelial neoplasia (PIN) were observed in the per-protocol population (n = 1,107). In a systematic review of males between the ages of 12 and 76 years at time of vaccination, Harder et al. (2018; 5,294 participants) reported vaccine efficacy of 61.9% against AIN grade 2 and 46.8% against AIN grade 3 lesions. No meaningful estimates were reported on vaccine efficacy or

effectiveness against PIN grade 2 or 3, and no data was reported for anal, penile, or head and neck squamous cell cancer.

Summary of findings regarding the clinical effectiveness of the HPV vaccine on anal intraepithelial neoplasia (AIN)/cancer in males vaccinated at any age: There is *a preponderance of evidence* that the HPV vaccine is effective at providing protection against HPV-related anogenital disease in males based on two studies and one systematic review.

Figure 4. Summary of Findings Regarding Findings on the Clinical Effectiveness of the HPV Vaccine on Anal Intraepithelial Neoplasia (AIN)/Cancer in Males Vaccinated at Any Age

Findings on the Clinical Effectiveness of the HPV Vaccine in Females and Males on Genital Warts

Findings on the clinical effectiveness of the HPV vaccine for the prevention anogenital warts in females when vaccinated before age 25

Drolet et al. (2019) reported significant decreases in anogenital wart diagnoses among females aged 15 to 19, 20 to 24 years, and 25 to 29 years in the first 4 years following the licensure of the quadrivalent HPV vaccine. Anogenital wart diagnoses decreased significantly among females aged 15 to 19 years (67%) and 20 to 24 years (54%) at time of vaccination. Three studies examined changes in anogenital wart diagnoses, following the implementation of the bivalent vaccine, and found a slight, nonsignificant decrease among females aged 15 to 19 and 20 to 24 years (Drolet et al., 2019). In a review of eight studies, Yakely et al. (2019) also reported consistent declines in prevalence of anogenital warts reported in females aged 25 years or younger after 2006 (when routine female HPV vaccination began in the United States).

Findings on the clinical effectiveness of the HPV vaccine for the prevention of anogenital warts in females when vaccinated over age 25

In a meta-analysis, Drolet et al. (2019) reported significant decreases in anogenital wart diagnoses among women aged 25 to 29 years (31%;15 studies) in the first 4 years following the implementation of the quadrivalent HPV vaccine but no difference in women 30 years or older at time of vaccination (14 studies).

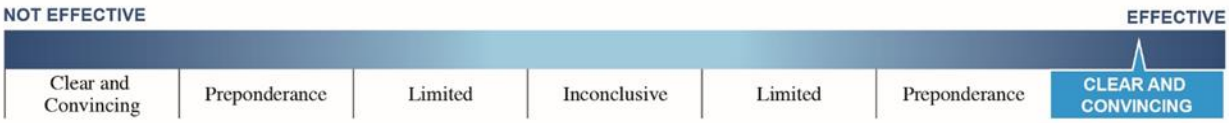
Findings on the clinical effectiveness of the HPV vaccine for the prevention anogenital warts in males

There are several studies in men that report protection from the HPV vaccine against anogenital warts related to high-risk HPV (Drolet et al., 2019; Goldstone et al., 2022; Olsson et al., 2020). With a median of 9.5 years follow-up after third vaccine dose, in males vaccinated between the ages of 16 and 23 years, incidence of external genital warts related to high-risk HPV was 0 incidence per 10,000 person-years versus 137/10,000 person-years (Goldstone et al., 2022). In an observational study, comparing before and after vaccination incidence, Olsson reported that at approximately 8 years after vaccination, for boys vaccinated between the ages of 9 and 15 years, there were no cases of genital warts in men related to the HPV vaccine types. In a meta-analysis of the population-level impact, Drolet et al. (2019) reported that anogenital wart diagnoses decreased significantly among boys aged 15 to 19 years (48%) and

among men aged 20 to 24 years (32%) 5 to 8 years after vaccination between pre-vaccination and post-vaccination time periods. Comparing trends before and after implementation of the HPV vaccine, Yakely also reported consistent declines in diagnoses reported in males aged 25 years or younger after 2006, when routine vaccination began in the United States (Yakely et al., 2019).

Summary of findings regarding the clinical effectiveness of the HPV vaccine for the prevention anogenital warts in females and males aged 26 or younger at the time of vaccination: There is *clear and convincing evidence* that the HPV vaccine is effective, based on two studies and two systematic reviews that HPV vaccines prevent HPV-related anogenital warts for females and males vaccinated at age 26 or younger. There is *insufficient* evidence that HPV vaccine is effective at preventing HPV-related anogenital warts after age 26.

Figure 5. Clinical Effectiveness of the HPV Vaccines for the Prevention Anogenital Warts in Females and Males Vaccinated at Age 26 or Younger



Potential Harms From AB 2516

When data are available, CHBRP estimates the marginal change in relevant harms associated with interventions affected by the proposed mandate. There is evidence to suggest that an increase in the use of the HPV vaccine could result in harm. Potential harms associated with the use of the HPV vaccine include side effects at the time of injection, including fever, headache, nausea, and/or muscle or joint pain (CDC, 2020b). In a combined analysis of seven trials, Moreira et al. (2016; 15,000 participants) reported that ≥5% individuals who received at least one dose of the 9-valent vaccine mild or moderate injection site reactions (pain, erythema, and swelling) and serious adverse events were reported occurred in <0.1 percent of participants. Despite the possible harms, *clear and convincing evidence* shows that the benefits of the HPV vaccine outweigh the harms.

Summary of Medical Effectiveness Findings

HPV vaccines are approved by the FDA for the prevention of the cervical cancer, genital warts, and some cancers of the vulva, vagina, anus, and oropharynx. Meta-analyses and systematic reviews have found *clear and convincing* evidence that high-risk HPV infection rates are lower in female populations that have been vaccinated against HPV at age 26 or younger and that vaccination reduces rates of cervical cancer, CIN 2+, CIN 3+, and AIS associated with any HPV strains. However, the evidence of effectiveness of the HPV vaccination in women vaccinated at age 27 or older is *limited*. There is *limited evidence* that the HPV vaccine is effective in preventing lesions caused by HPV 16/18 for women vaccinated after age 27. There are no studies for women vaccinated after age 27 who are HPV negative at baseline on CIN 2+, CIN 3+, and AIS associated with any HPV strains. The risks of CIN 2+ associated with any HPV type are similar between vaccinated and unvaccinated females in populations with unknown HPV status at time of vaccination. There is *insufficient evidence* that the HPV vaccine, given at any age, is effective for the prevention of oral or oropharyngeal HPV infections. There is a *preponderance of evidence* that the HPV vaccine is effective at providing protection against HPV-related anogenital disease in males vaccinated at any. There is *clear and convincing evidence* that the HPV vaccines prevent HPV-related anogenital warts for females and males vaccinated at age 26 or younger.

Table 6. Summary of Effectiveness of the HPV Vaccine in Preventing HPV Infection and Related Cancers, by Age at Vaccination

	Vaccinated at age 26 or younger	Vaccinated at age 27 or older
Cervical cancer (females)	Clear and convincing evidence, effective	Limited evidence, effective
CIN (females)	Clear and convincing evidence, effective	Limited evidence, effective
AIS (females)	Clear and convincing evidence, effective	Limited evidence, effective
Oral or oropharyngeal infections (females/males)	Insufficient evidence	Insufficient evidence
Anogenital disease (males)	Preponderance of evidence, effective	Preponderance of evidence, effective
Anogenital warts (females/males)	Clear and convincing evidence, effective	Insufficient evidence

Source: California Health Benefits Review Program, 2022.
Notes: Anogenital diseases include anal intraepithelial neoplasia (AIN) and anal cancer. Anogenital warts are the same as genital warts.
Key: AIS= adenocarcinoma in situ; CIN= high-grade cervical intraepithelial neoplasia.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, AB 2516 would require coverage and prohibit health plans and health policies regulated by DMHC or CDI from imposing cost sharing on the HPV vaccine for persons for whom the FDA has approved the vaccine. Since 2014, coverage has been required and cost sharing has been prohibited for most enrollees aged 9 to 26 years under the ACA.[44] In 2019, the federal Advisory Committee on Immunization Practices (ACIP) recommended shared clinical decision-making for the HPV vaccine for enrollees aged 27 to 45 years and placed this recommendation on the adult vaccine schedule. For enrollees aged 9 to 45 years in nongrandfathered plans and policies, the HPV vaccine is required to be covered without cost sharing.

AB 2516 also includes a requirement for the Family PACT program to cover administration of the HPV vaccine for clients it serves, as mentioned in the *Policy Context* section. Family PACT is a publicly funded program targeted at family planning services, and does not provide comprehensive health insurance coverage. According to its eligibility requirements (Family PACT, 2022), enrollees in Family PACT may have other health insurance coverage as long as that coverage does not include contraception and reproductive health services. Family PACT is therefore not included as a DMHC-regulated plan or CDI-regulated policy that is impacted by health insurance benefit mandates in the CHBRP Cost and Coverage Model. CHBRP is also unable to estimate how many Family PACT enrollees are vaccinated with the HPV vaccine at baseline.

In addition to commercial enrollees, more than 70% of enrollees associated with the California Public Enrollees' Retirement System (CalPERS) and more than 80% of Medi-Cal beneficiaries are enrolled in DMHC-regulated plans.[45] AB 2516 would not impact enrollees in the DMHC-regulated Medi-Cal managed care plans or CalPERS plans, as they already have coverage without cost sharing for the HPV vaccine at baseline.

This section reports the potential incremental impacts of AB 2516 on estimated baseline benefit coverage, utilization, and overall cost.

Analytic Approach and Key Assumptions

AB 2516 has differential impacts by age, due to the different federal guidelines for those aged 9 to 26 years and 27 to 45 years. For those aged 9 to 26 years, with cost sharing prohibited for nongrandfathered plans under the ACA, a natural experiment existed for researchers to study the impact of eliminating cost sharing for this age group. The research consensus is that eliminating cost sharing had some impact on increasing utilization of the HPV vaccine but did not increase utilization to the level of reaching all who are eligible for vaccination (Agénor et al., 2020; Corriero et al., 2018; Hawkins et al., 2021b; Lipton & Decker, 2015; Osazuwa-Peters et al., 2020). Based on this research, CHBRP assumed that the rate of receiving the HPV vaccine for enrollees aged 9 to 26 years in grandfathered plans or policies that had cost sharing at baseline would change population-level utilization of HPV vaccines to match the rate of the population aged 9 to 26 years without cost sharing at baseline.

Federal guidelines state that administration of the HPV vaccine to enrollees aged 27 to 45 years would be based on "shared clinical decision-making" with the enrollee (Meites et al., 2019), which would include detailed investigation into the enrollee's history of number of prior sexual partners, or whether they have any prior sexual exposure at all.[46] The enrollee's potential benefit from HPV vaccination also includes their personal assessment of their own risk of future exposure.[53] Doctors in the United States are not likely to recommend HPV vaccination to their patients aged 27 to 45 years, mostly due to not viewing it as

[44] Grandfathered plans and policies are not required to cover the HPV vaccine and are not required to provide coverage without cost sharing.
[45] For more detail, see CHBRP's *Estimates of Sources of Health Insurance in California for 2023*, a resource available at http://chbrp.org/other_publications/index.php.
[46] Personal communication with Dr. George Sawaya, professor, UC San Francisco, on March 11, 2022.

beneficial or applicable (Hurley et al., 2021; Petrusek et al., 2020). Finally, some plans and policies may place prior authorization requirements on administration of the HPV vaccine series, which may deter some enrollees from getting the vaccination due to delay in approval from the prior authorization process.[53] These factors combine to limit the potential impact on utilization of the HPV vaccine for enrollees aged 27 to 45 years and likely have a greater impact on whether the enrollee decides to get vaccinated than cost sharing. CHBRP therefore assumes that utilization of the HPV vaccine among enrollees aged 27 to 45 years is unlikely to measurably increase due to reduced cost sharing postmandate, if AB 2516 is enacted.

CHBRP administered a survey of major health insurance carriers in California to determine baseline coverage for HPV vaccines with no cost sharing, including age-based differentiation, differences between grandfathered and nongrandfathered plans, and prior authorization requirements. Change postmandate was determined using the CHBRP Cost and Coverage Model and Milliman claims data.

CHBRP is unable to determine whether enrollees who receive an HPV vaccine shot complete the full series of vaccination as recommended based on their age (either two or three doses), because these vaccine shots may occur over multiple plan years. CHBRP presents utilization of HPV vaccine shots per 1,000 enrollees for a single plan year. Should an enrollee receive multiple vaccine shots within one plan year, two instances of utilization would be present within claims data analyzed by CHBRP.

As mentioned in the *Policy Context* section, Family PACT provided services to almost 700,000 individuals in 2019. The number of persons served by Family PACT in 2023 will likely be smaller. CHBRP is unable to determine how many of these future recipients have already received the HPV vaccine and how many would receive this service should AB 2516 pass and provide coverage of the vaccine through Family PACT. As mentioned in the *Policy Context* section, Family PACT only provides services if a person seeking services has no other coverage for the eligible services. CHBRP does not expect a reduction in HPV vaccines under plans and policies regulated by DMHC or CDI as a result of the Family PACT expansion.

For further details on the underlying data sources and methods used in this analysis, please see Appendix C.

Baseline and Postmandate Benefit Coverage

At baseline, 99.6% of enrollees have coverage that is fully compliant with AB 2516 (i.e., coverage of the HPV vaccine without cost sharing). Enrollees without coverage or coverage with cost sharing for the HPV vaccine at baseline have DMHC-regulated plans or CDI-regulated policies that are “grandfathered” under the provisions of the ACA, and so are able to retain cost sharing for vaccinations. Postmandate, 100% of enrollees would have coverage for HPV vaccines with no cost sharing (see Table 1).

Baseline and Postmandate Utilization

Utilization was determined using the Milliman claims database, with baseline and postmandate estimated for the California insured population using the CHBRP Cost and Coverage Model (see Appendix C for detailed description of inputs). At baseline, the HPV vaccine has a utilization rate that varies slightly among males and females, even within the same age group. Among those aged 9 to 26 years, there are 120.9 HPV vaccine shots per 1,000 female enrollees at baseline, and there are 113 HPV vaccine shots per 1,000 male enrollees (see Table 1). For older enrollees aged 27 to 45 years, among females there are 6.1 HPV vaccine shots per 1,000 enrollees and among males, there are 4.4 HPV vaccine shots per 1,000 enrollees.

Utilization for males and females aged 9 to 26 years would increase slightly postmandate if AB 2516 were enacted (see Table 1), as the utilization rate for the 0.4% of enrollees in DMHC-regulated plans or CDI-regulated policies who previously had cost sharing or did not have coverage would increase to match those that had coverage without cost sharing at baseline. CHBRP estimates that postmandate utilization per 1,000 enrollees would increase by 1.5 vaccine shots per 1,000 females aged 9 to 26 years to 122.3, and by 1.3 vaccines per 1,000 males aged 9 to 26 years to 114.4. CHBRP estimates that the change in benefit coverage and reduction in cost sharing for those aged 27 to 45 years would not result in an increase in utilization since the medical guidelines for shared clinical decision-making will keep utilization down to those who are both medically eligible and want to obtain the series of HPV vaccination shots. Postmandate, the average utilization rate for the HPV vaccine for both males and females aged 27 to 45 years will have no measurable change.

Baseline and Postmandate Per-Unit Cost

Per-unit costs were estimated using Milliman claims data and the CHBRP Cost and Coverage Model. At baseline, per-unit costs varies by type of insurance plan or policy (see Table 1). DMHC-regulated commercial or CalPERS plans and CDI-regulated commercial policies have an average per-unit cost of $360.00 per HPV vaccine shot. For DMHC-regulated Medi-Cal managed care plans, there is an average per-unit cost of $110.09 per HPV vaccine shot.

Postmandate, the average per-unit costs would remain constant, as utilization is not expected to increase enough to significantly change the demand for HPV vaccines.

Baseline and Postmandate Expenditures

Table 8 and Table 9 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 2516 would increase total net annual expenditures by $3,834,000 or 0.0026% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a $3,975,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a decrease of $141,000 in enrollee expenses for covered and/or noncovered benefits.

Premiums

Changes in premiums as a result of AB 2516 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 8, and Table 9), with health insurance that would be subject to AB 2516.

Among privately funded DMHC-regulated health plans, CHBRP estimates premium increases postmandate ranging from $0.0014 PMPM for large-group plans and policies to $0.0705 PMPM for small-group plans. Among privately funded CDI-regulated policies, CHBRP estimates premium increases postmandate ranging from $0.0002 PMPM for large-group policies to $0.5246 PMPM for individual policies, with no change to premiums for small-group policies. All changes occur for enrollees in grandfathered plans and policies.

Plans and policies purchased either through Covered California or that are off-exchange, mirror plans are currently required to cover the HPV vaccination without cost sharing; therefore, there is no impact for enrollees in these plans and policies.

Among publicly funded DMHC-regulated health plans, both CalPERS plans and Medi-Cal managed care plans would have no change in premiums.

Enrollee Expenses

AB 2516–related reductions in cost sharing for covered benefits (deductibles, copays, etc.) and out-of-pocket expenses for noncovered benefits would vary by market segment. Note that such reductions are related to the number of enrollees (see Table 1, Table 8, and Table 9) with health insurance that would be subject to AB 2516 expected to get HPV vaccination without cost sharing during the year after enactment.

It is possible that some enrollees incurred expenses related to HPV vaccines for which coverage was denied, but CHBRP cannot estimate the frequency with which such situations occur and so cannot offer a calculation of impact.

Among privately funded DMHC-regulated health plans, CHBRP estimates decreases in enrollee expenses postmandate ranging from $0.0011 PMPM for large-group plans to $0.0010 PMPM for small-group plans, with no changes for individual plans. Among privately funded CDI-regulated policies, CHBRP estimates decreases in enrollee expenses postmandate ranging from $0.0002 PMPM for large-group policies to $0.0007 PMPM for individual policies, with no change for small-group policies. These decreases in enrollee expenses reflect that only grandfathered plans would change their existing cost sharing postmandate.

Among publicly funded DMHC-regulated health plans, both CalPERS plans and Medi-Cal managed care plans would have no change.

Average enrollee expenses per user

For enrollees with coverage for HPV vaccines at baseline in privately funded large-group DMHC-regulated plans or CDI-regulated policies, 0.0077% of enrollees would experience an average decrease in cost sharing for covered services of $168 (see Table 7). In small-group DMHC-plans or CDI-regulated policies, 0.0031% of enrollees would see a reduction of an average $262 in cost sharing, and in individual plans or policies, 0.0010% of enrollees would see an average of $102 in reduced cost sharing. CHBRP estimates are based on claims data and may underestimate the cost savings for enrollees due to carriers' ability to negotiate discounted rates that are unavailable to patients and their families.

Among enrollees with coverage at baseline, cost sharing was present for 0.7 vaccine shots per 1,000 females aged 9 to 26 years, 1.1 vaccines per 1,000 males aged 9 to 26 years, 0.1 vaccines per 1,000 females aged 27 to 45 years, and 0.2 vaccines per 1,000 males aged 27 to 45 years. Postmandate, no enrollees would have cost sharing for HPV vaccines. This equates to approximately 9,400 vaccine shots with cost sharing for HPV vaccines at baseline.

Table 7. Impact of AB 2516 on Average Enrollee Out-of-Pocket Expenses

	Large Group	Small Group	Individual	CalPERS HMO	Medi-Cal HMO
% of Enrollees with Out-of-Pocket Expenses Who Would Have a Reduction Due to AB 2516 (a)	0.0077%	0.0031%	0.0010%	0.0000%	0.0000%
Avg. Annual Out-of-Pocket Expenses Reduction for Enrollees	$168	$262	$102	$0	0

Source: California Health Benefits Review Program, 2022.

Notes: Average enrollee out-of-pocket expenses include expenses for both covered and noncovered benefits.

(a) Not including impacts on premiums.

(b) Benefit coverage for Medi-Cal beneficiaries does not generally include any cost sharing.

For enrollees with coverage for HPV vaccines with cost sharing at baseline, the average annual out-of-pocket amount presented in Table 7 reflects a mix of plan design features that affect the level of cost sharing. An enrollee who has not yet met their deductible would be responsible for the entire cost of HPV vaccination, while an enrollee who has met their out-of-pocket maximum for the year would not be responsible for the cost of vaccination even if a copayment or coinsurance would have otherwise been applied. CHBRP is able to determine that among the cost sharing reported above, on average, 81% is due to deductible, 17% is due to coinsurance, and 2% is due to copayments. CHBRP is unable to determine each individual enrollee's reduction in cost sharing.

Potential Cost Offsets or Savings in the First 12 Months After Enactment

CHBRP does not project any cost offsets or savings in health care in the first year postmandate that would result because of the enactment of provisions in AB 2516. The HPV vaccination prevents a range of diseases, most notably genital warts and cervical cancer, but it is highly unlikely that the increases in HPV vaccines would prevent illness that would otherwise occur within the first year. This vaccination is targeted towards lifetime prevention, and any cost offsets from disease prevention would occur after the first year postmandate (see the *Long-Term Impacts* section).

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, related considerations for policymakers are discussed below.

Postmandate Changes in the Number of Uninsured Persons

Because the change in average premiums does not exceed 1% for any market segment (see Table 1, Table 8, and Table 9), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 2516.

Changes in Public Program Enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of AB 2516.

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

With a lack of coverage in some grandfathered plans, some of these enrollees may have turned to Family PACT for reproductive services, if their main health insurance plan also did not include adequate coverage for reproductive services. CHBRP is unable to determine, however, how many Family PACT enrollees may be in that category, or whether they received HPV vaccination through their main health insurance plan, with or without cost sharing.

Table 8. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2023

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs (b)*	*MCMC (Under 65) (c)(f)*	*MCMC (65+) (c)(f)*	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,317,000	2,125,000	2,758,000	881,000	7,158,000	876,000	485,000	44,000	166,000	22,810,000
Total enrollees in plans/policies subject to AB 2516	8,317,000	2,125,000	2,758,000	881,000	7,158,000	876,000	485,000	44,000	166,000	22,810,000
Premiums										
Average portion of premium paid by employer	$407.24	$369.14	$0.00	$557.65	$238.69	$521.94	$465.60	$379.33	$0.00	$84,852,462,000
Average portion of premium paid by employee	$166.59	$204.69	$691.58	$113.48	$0.00	$0.00	$228.48	$246.41	$572.88	$48,534,724,000
Total premium	**$573.83**	**$573.83**	**$691.58**	**$671.13**	**$238.69**	**$521.94**	**$694.08**	**$625.74**	**$572.88**	**$133,387,186,000**
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	$48.46	$124.44	$175.87	$58.77	$0.00	$0.00	$146.18	$200.65	$200.15	$15,807,011,000
Expenses 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	**$622.29**	**$698.27**	**$867.45**	**$729.89**	**$238.69**	**$521.94**	**$840.26**	**$826.39**	**$773.02**	**$149,194,197,000**

Source: California Health Benefits Review Program, 2022.

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

(b) Approximately 51.7% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 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 covered by insurance at baseline. 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.

(f) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

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 9. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2023

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs (b)*	*MCMC (Under 65) (c)(f)*	*MCMC (65+) (c)(f)*	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	8,317,000	2,125,000	2,758,000	881,000	7,158,000	876,000	485,000	44,000	166,000	22,810,000
Total enrollees in plans/policies subject to AB 2516	8,317,000	2,125,000	2,758,000	881,000	7,158,000	876,000	485,000	44,000	166,000	22,810,000
Premiums										
Average portion of premium paid by employer	$0.0010	$0.0453	$0.0000	$0.0000	$0.0000	$0.0000	$0.0001	$0.0000	$0.0000	$1,253,000
Average portion of premium paid by employee	$0.0004	$0.0251	$0.0301	$0.0000	$0.0000	$0.0000	$0.0001	$0.0000	$0.5253	$2,722,000
Total premium	$0.0014	$0.0705	$0.0301	$0.0000	$0.0000	$0.0000	$0.0002	$0.0000	$0.5253	**$3,975,000**
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	-$0.0011	-$0.0010	$0.0000	$0.0000	$0.0000	$0.0000	-$0.0002	$0.0000	-$0.0007	-$141,000
Expenses 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	$0.0002	$0.0695	$0.0300	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.5246	**$3,834,000**
Percent change										
Premiums	0.0002%	0.0123%	0.0043%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0917%	0.0030%
Total expenditures	0.0000%	0.0100%	0.0035%	0.0000%	0.0000%	0.0000%	0.0000%	0.0000%	0.0679%	0.0026%

Source: California Health Benefits Review Program, 2022.

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

(b) Approximately 51.7% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 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 covered by insurance at baseline. 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.

(f) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

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, AB 2516 would require coverage without cost sharing of the HPV vaccine for persons for whom the vaccine is FDA-approved for enrollees in state-regulated plans and policies. Additionally, AB 2516 would require coverage of the HPV vaccine by Family PACT.

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[47] of AB 2516 on HPV vaccination rates and potential harms. See *Long-Term Impacts* for discussion of disparities and social determinants of health.

Estimated Public Health Outcomes

As presented in the *Medical Effectiveness* section, there is *clear and convincing* evidence that the HPV vaccine is effective at preventing high-grade cervical intraepithelial neoplasia (CIN), adenocarcinoma in situ (AIS), and cervical cancer in females vaccinated at age 26 or younger and who are HPV negative before starting the vaccine series. For males who were vaccinated at any age, there is *a preponderance of evidence* that the HPV vaccine is effective at protecting against HPV-related anogenital disease. There is also *clear and convincing* evidence that the HPV vaccine is effective at preventing genital warts in females and males vaccinated at age 26 or younger.

For females aged 27 and older at vaccination, evidence is *limited* that the HPV vaccine protects against high-grade precancerous changes of the cervix. For males and females aged 9 to 45 years, there is *insufficient* evidence that the HPV vaccine prevents oral or oropharyngeal cancers.

As presented in *Benefit Coverage, Utilization, and Cost Impacts*, AB 2516 would eliminate cost sharing for all enrollees in DMHC-regulated plans and CDI-regulated policies. At baseline, 99.6% of enrollees currently have coverage for the HPV vaccine without cost sharing. The 0.41% of enrollees who have coverage with cost sharing or are without coverage are enrolled in grandfathered health plans and policies. Postmandate, approximately 4,078 additional vaccinations will occur among male enrollees and 4,367 additional vaccinations will occur among female enrollees aged 9 to 26 because of increased coverage and reduced cost sharing. No measurable increase in HPV vaccination of enrollees aged 27 to 45 years is expected due to changes in cost sharing postmandate. Average cost sharing would decrease in privately funded DMHC-regulated or CDI-regulated policies with cost sharing for the HPV vaccine from $168 for large group, $262 for small group, and $102 for individual plans, for males and females aged 9 to 26 years at baseline to $0 postmandate. Approximately 9,400 enrollees have cost sharing for the HPV vaccine at baseline; postmandate, no enrollees would have cost sharing for the HPV vaccine.

In the first year postmandate, AB 2516 would have no measurable impact on public health. Approximately 8,500 additional vaccines are projected to occur among enrollees (as described above) postmandate. As with many vaccines whose effects manifest over a longer timeframe, the effects of vaccination in the first year postmandate would be minimal. Although the HPV vaccine is found to be medically effective, CHBRP concludes that passage of AB 2516 would have no measurable short-term public health impact due to minimal change in overall utilization and lack of manifest vaccine effects in the short term. For this reason, CHBRP also concludes that AB 2516 would have no measurable impact on disparities in vaccination status or health outcomes (by sex, race/ethnicity, or sexual orientation/gender identity). It also would have no measurable impact on premature death and societal economic losses.

At the person level, one potentially detectable vaccine impact in the first year following vaccination would be a potential reduction in genital warts. Postmandate, it is expected that an additional 8,445 vaccinations would occur among persons aged 9 to 26 years and it is possible that some enrollees aged 27 to 45 years may choose to receive the HPV vaccine postmandate (but cannot be measured in CHBRP

[47] CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

estimates). While there is *clear and convincing evidence* that the HPV vaccine is effective at preventing genital warts and some cancers in both males and females who receive the vaccine before the age of 26, there is less evidence that enrollees aged 27 and older could expect the same degree of protection.

While elimination of cost sharing eliminates a barrier for a small group of enrollees who currently are subject to cost sharing, other barriers to HPV vaccination may continue to persist postmandate. These may include prior authorization requirements, lack of clinician recommendation, transportation issues to complete the entire vaccine series, parental disagreement about whether or not a minor enrollee should get the vaccine, or individual decisions not to receive the vaccine.

AB 2516's requirement for Family PACT to provide the HPV vaccine would likely increase utilization, although CHBRP is unable to estimate how many additional persons would receive the vaccine. However, as mentioned in the *Policy Context* section, enrollees of Family PACT are likely limited to uninsured Californians not currently eligible for Medi-Cal or for other coverage. Because there are multiple programs through which Californians under age 18 can receive the HPV vaccine free of charge, a small number of persons (mostly over age 18) using Family PACT would likely be eligible to receive the HPV vaccine. Therefore, an increase in utilization of the HPV vaccine among this group is unlikely to result in a public health impact.

Even though there is evidence that the HPV vaccine is effective in preventing HPV infections and related cancers, because there is already broad benefit coverage of the HPV vaccine without cost sharing and a limited increase in utilization of the vaccine postmandate, CHBRP finds there is no measurable public health impact from AB 2516. For this reason, CHBRP also concludes that AB 2516 would have no measurable impact on disparities in vaccination status or health outcomes.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of AB 2516, 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

The increases in utilization of the HPV vaccine among enrollees in DMHC-regulated plans or CDI-regulated policies that were grandfathered and had cost sharing at baseline would lead to future decreases in cervical cancer, as well as other HPV-related genital diseases. In females, research has shown a significant decrease in non-cancer HPV-related disease at 3 to 5 years post-vaccination (Muñoz et al., 2010), and a projected decrease of up to 59% of HPV-related cervical cancer over the long-term (Laprise et al., 2020). The decreases in HPV-related disease and cancer would lead to decreases in tests, treatments, and services related to these conditions over time.

Cost Impacts

Reductions in the incidence of HPV-related diseases, including cervical cancer, would be associated with decreases in costs of tests, treatments, and services related to those conditions. CHBRP is unable to quantify the costs associated with the range of these conditions. It is clear, however, that the literature indicates a cost savings for a comprehensive HPV vaccination program over time.

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 (SDOH), premature death, and economic loss.

While HPV vaccination has been shown to reduce precancerous cervical cell changes and is considered likely to reduce cancers related to high-risk HPV infections 5 or more years following vaccination, CHBRP concludes that passage of AB 2516 would have no measurable long-term public health impact due to minimal changes in utilization of the HPV vaccine. In the case of AB 2516, CHBRP estimates the change in utilization of the HPV vaccine within the first year postmandate would be 1.35%. The numbers of additional individuals aged 9 to 26 years who would receive the vaccine after the first year postmandate cannot be accurately projected. As noted above, there are numerous barriers to HPV vaccination beyond cost sharing. If vaccination in this age group is obtained prior to HPV infection, genital warts, cervical precancers and cancers are described in *Medical Effectiveness*. The long-term public health impacts are mostly isolated to those vaccinated at age 9 to 26 years who are enrolled in a grandfathered health plan or policy who later receive the vaccine due to the elimination of cost sharing. The larger population may benefit from reduced transmission of the disease in the larger community.

Impacts on Disparities and the Social Determinants of Health[48]

In the case of AB 2516, evidence shows that disparities by sex, race/ethnicity, or sexual orientation/gender identity exist and likely contribute to uneven distribution of genital warts infections and certain cancers in later life. Due to the lack of measurable long-term public health impact, CHBRP projects no changes in these disparities that would be attributable to AB 2516.

One provision of this bill that could not be quantified by CHBRP was the expansion of services covered in Family PACT. As described in *Policy Context*, Family PACT provides free family planning services for approximately 700,000 Californians with incomes below 200% of the federal poverty level (FPL) and no other coverage for family planning services. Because Family PACT primarily serves low-income persons of color in California regardless of immigration status, there is the potential to increase vaccination rates among this population. However, the extent to which vaccination rates would increase and the resulting impact on disparities and SDOH is unknown.

[48] 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 22, 2022, the California Assembly Committee on Health requested that CHBRP analyze AB 2516.

ASSEMBLY BILL **NO. 2516**

Introduced by Assembly Member Aguiar-Curry

February 17, 2022

An act to amend Section 1367.66 of the Health and Safety Code, to amend Section 10123.18 of the Insurance Code, and to amend Section 14132 of the Welfare and Institutions Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 2516, as introduced, Aguiar-Curry. Health care coverage: human papillomavirus.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, 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 requires a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2002, to provide coverage for an annual cervical cancer screening test, including a human papillomavirus (HPV) screening test that is approved by the federal Food and Drug Administration (FDA).

Existing law provides for the Medi-Cal program, administered by the State Department of Health Care Services and under which health care services are provided to low-income individuals pursuant to a schedule of benefits. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions. Existing law also establishes the Family Planning, Access, Care, and Treatment (Family PACT) Program, administered by the Office of Family Planning within the department, under which comprehensive clinical family planning services are provided to a person who has a family income at or below 200% of the federal poverty level, and who is eligible to receive these services.

This bill would require a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2023, to provide coverage without cost sharing for the HPV vaccine for persons for whom the vaccine is FDA approved. 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 bill would also expand comprehensive clinical family

planning services under the Family PACT Program to include the HPV vaccine for persons for whom it is FDA approved.

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

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

SECTION 1. Section 1367.66 of the Health and Safety Code is amended to read:

~~1367.66. Every individual or group~~

1367.66. (a) A health care service plan contract, except for a specialized health care service plan, that is issued, amended, or renewed on or after January 1, 2002, and that includes coverage for treatment or surgery of cervical cancer shall also be deemed to shall provide coverage for an annual cervical cancer screening test upon the referral of the patient's physician and surgeon, a nurse practitioner, or a certified nurse midwife, providing care to the patient and operating within the scope of practice otherwise permitted for the licensee.

~~The~~

(1) The coverage for an annual cervical cancer screening test provided pursuant to this section shall include the conventional Pap test, a human papillomavirus screening test that is approved by the federal Food and Drug ~~Administration,~~ *Administration (FDA),* and the option of any cervical cancer screening test approved by the ~~federal Food and Drug Administration,~~ *FDA,* upon the referral of the patient's health care provider.

~~Nothing in this section shall be construed to~~

(2) This subdivision does not establish a new mandated benefit or to prevent application of deductible or copayment provisions in an existing plan contract. The Legislature intends in this section to provide that cervical cancer screening services are deemed to be covered if the plan contract includes coverage for cervical cancer treatment or surgery.

(b) A health care service plan contract, except for a specialized health care service plan, issued, amended, or renewed on or after January 1, 2023, shall provide coverage for the human papillomavirus vaccine for enrollees for whom the vaccine is approved by the FDA. A health care service plan contract shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on the coverage provided pursuant to this subdivision.

SEC. 2. Section 10123.18 of the Insurance Code is amended to read:

10123.18. (a) every individual or group policy of health insurance that provides coverage for hospital, medical, or surgical benefits, that is *a health insurance policy* issued, amended, or renewed, *renewed* on or after january 1, 2002, and that includes coverage for treatment or surgery of cervical cancer shall also be deemed to *shall* provide coverage, upon the referral of a patient's physician and surgeon, a nurse practitioner, or a certified nurse midwife, providing care to the patient and operating within the scope of practice otherwise permitted for the licensee, for an annual cervical cancer screening test.

~~The~~

(1) The coverage for an annual cervical cancer screening test provided pursuant to this section shall include the conventional Pap test, a human papillomavirus screening test that is approved by the federal Food and Drug ~~Administration,~~ *Administration (FDA)* and the option of any cervical cancer screening test approved by the ~~federal Food and Drug Administration,~~ *FDA*, upon the referral of the patient's health care provider.

~~Nothing in this section shall be construed to~~

(2) This subdivision does not require an individual or group policy to cover treatment or surgery for cervical cancer or to prevent application of deductible or copayment provisions contained in the policy or certificate, ~~nor shall this section be construed to~~ *and does not* require that coverage under an individual or group policy be extended to any other procedures.

(b) A health insurance policy issued, amended, or renewed on or after January 1, 2023, shall provide coverage for the human papillomavirus vaccine for insureds for whom the vaccine is approved by the FDA. A health insurance policy shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on the coverage provided pursuant to this subdivision.

~~(b)~~

(c) This section shall not apply to vision only, dental only, accident only, specified disease, hospital indemnity, Medicare supplement, CHAMPUS supplement, long-term care, or disability income insurance. For accident only, hospital indemnity, or specified disease insurance, coverage for benefits under this section shall apply only to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy or certificate. ~~Nothing in this section shall be construed as imposing~~ *This section does not impose* a new benefit mandate on accident only, hospital indemnity, or specified disease insurance.

SEC. 3. Section 14132 of the Welfare and Institutions Code is amended to read:

14132. The following is the schedule of benefits under this chapter:

[Sections (a) – (z) remain unchanged.]

(aa) (1) There is hereby established in the department a program to provide comprehensive clinical family planning services to any person who has a family income at or below 200 percent of the federal poverty level, as revised annually, and who is eligible to receive these services pursuant to the waiver identified in paragraph (2). This program shall be known as the Family Planning, Access, Care, and Treatment (Family PACT) Program.

(2) The department shall seek a waiver in accordance with Section 1315 of Title 42 of the United States Code, or a state plan amendment adopted in accordance with Section 1396a(a)(10)(A)(ii)(XXI) of Title 42 of the United States Code, which was added to Section 1396a of Title 42 of the United States Code by Section 2303(a)(2) of the federal Patient Protection and Affordable Care Act (PPACA) (Public Law 111-148), for a program to provide comprehensive clinical family planning services as described in paragraph (8). Under the waiver, the program shall be operated only in accordance with the waiver and the statutes and regulations in paragraph (4) and subject to the terms, conditions, and duration of the waiver. Under the state plan amendment, which shall replace the waiver and shall be known as the Family PACT successor state plan amendment, the program shall be operated only in accordance with this subdivision and the statutes and regulations in paragraph (4). The state shall use the standards and processes imposed by the state on January 1, 2007, including the application of an eligibility discount factor to the extent required by the federal Centers for Medicare and Medicaid Services, for purposes of determining eligibility as permitted under Section 1396a(a)(10)(A)(ii)(XXI) of Title 42 of the United States Code. To the extent that federal financial participation is available, the program shall continue to conduct education, outreach, enrollment, service delivery, and evaluation services as specified under the waiver. The services shall be provided under the program only if the waiver and, when applicable, the successor state plan amendment are approved by the federal Centers for Medicare and Medicaid Services and only to the extent that federal financial participation is available for the services. This section does not prohibit the department from seeking the Family PACT successor state plan amendment during the operation of the waiver.

(3) Solely for the purposes of the waiver or Family PACT successor state plan amendment and notwithstanding any other law, the collection and use of an individual's social security number shall be necessary only to the extent required by federal law.

(4) Sections 14105.3 to 14105.39, inclusive, 14107.11, 24005, and 24013, and any regulations adopted under these statutes shall apply to the program provided for under this subdivision. No other law under the Medi-Cal program or the State-Only Family Planning Program shall apply to the program provided for under this subdivision.

(5) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, without taking regulatory action, the provisions of the waiver after its approval by the federal Centers for Medicare and Medicaid Services and the provisions of this section by means of an all-county letter or similar instruction to providers. Thereafter, the department shall adopt regulations to implement this section and the approved waiver in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. Beginning six months after the effective date of the act adding this subdivision, the department shall provide a status report to the Legislature on a semiannual basis until regulations have been adopted.

(6) If the Department of Finance determines that the program operated under the authority of the waiver described in paragraph (2) or the Family PACT successor state plan amendment is no longer cost effective, this subdivision shall become inoperative on the first day of the first month following the issuance of a 30-day notification of that determination in writing by the Department of Finance to the chairperson in each house that considers appropriations, the chairpersons of the committees, and the appropriate subcommittees in each house that considers the State Budget, and the Chairperson of the Joint Legislative Budget Committee.

(7) If this subdivision ceases to be operative, all persons who have received or are eligible to receive comprehensive clinical family planning services pursuant to the waiver described in paragraph (2) shall receive family planning services under the Medi-Cal program pursuant to subdivision (n) if they are otherwise eligible for Medi-Cal with no share of cost, or shall receive comprehensive clinical family planning services under the program established in Division 24 (commencing with Section 24000) either if they are eligible for Medi-Cal with a share of cost or if they are otherwise eligible under Section 24003.

(8) For purposes of this subdivision, "comprehensive clinical family planning services" means the process of establishing objectives for the number and spacing of children, and selecting the means by which those objectives may be achieved. These means include a broad range of acceptable and effective methods and services to limit or enhance fertility, including contraceptive methods, federal Food and Drug Administration-approved contraceptive drugs, devices, and supplies, natural family planning, abstinence methods, and basic, limited fertility management. Comprehensive clinical family planning services include, but are not limited to, preconception counseling, maternal and fetal health counseling, general reproductive health care, including diagnosis and treatment of infections and conditions, including cancer, that threaten reproductive capability, medical family planning treatment and procedures, including supplies and followup, and informational, counseling, and educational services. Comprehensive clinical family planning services shall not include abortion, pregnancy testing solely for the purposes of referral for abortion or services ancillary to abortions, or pregnancy care that is not incident to the diagnosis of pregnancy. Comprehensive clinical family planning services shall be subject to utilization control and include all of the following:

(A) Family planning related services and male and female sterilization. Family planning services for men and women shall include emergency services and services for complications directly related to the contraceptive method, federal Food and Drug Administration-approved contraceptive drugs, devices, and supplies, and followup, consultation, and referral services, as indicated, which may require treatment authorization requests.

(B) All United States Department of Agriculture, federal Food and Drug Administration-approved contraceptive drugs, devices, and supplies that are in keeping with current standards of practice and from which the individual may choose.

(C) Culturally and linguistically appropriate health education and counseling services, including informed consent, that include all of the following:

(i) Psychosocial and medical aspects of contraception.

(ii) Sexuality.

(iii) Fertility.

(iv) Pregnancy.

(v) Parenthood.

(vi) Infertility.

(vii) Reproductive health care.

(viii) Preconception and nutrition counseling.

(ix) Prevention and treatment of sexually transmitted infection.

(x) Use of contraceptive methods, federal Food and Drug Administration-approved contraceptive drugs, devices, and supplies.

(xi) Possible contraceptive consequences and followup.

(xii) Interpersonal communication and negotiation of relationships to assist individuals and couples in effective contraceptive method use and planning families.

(D) A comprehensive health history, updated at the next periodic visit (between 11 and 24 months after initial examination) that includes a complete obstetrical history, gynecological history, contraceptive history, personal medical history, health risk factors, and family health history, including genetic or hereditary conditions.

(E) A complete physical examination on initial and subsequent periodic visits.

(F) Services, drugs, devices, and supplies deemed by the federal Centers for Medicare and Medicaid Services to be appropriate for inclusion in the program.

(G) The human papillomavirus vaccine for persons for whom it is approved by the federal Food and Drug Administration (FDA).

~~(G)~~

(H) (i) Home test kits for sexually transmitted diseases, including any laboratory costs of processing the kit, that are deemed medically necessary or appropriate and ordered directly by an enrolled Medi-Cal or Family PACT clinician or furnished through a standing order for patient use based on clinical guidelines and individual patient health needs.

(ii) For purposes of this subparagraph, "home test kit" means a product used for a test recommended by the federal Centers for Disease Control and Prevention guidelines or the United States Preventive Services Task Force that has been CLIA-waived, FDA-cleared or -approved, or developed by a laboratory in accordance with established regulations and quality standards, to allow individuals to self-collect specimens for STDs, including HIV, remotely at a location outside of a clinical setting.

(iii) Reimbursement under this subparagraph shall be contingent upon the addition of codes specific to home test kits in the Current Procedural Terminology or Healthcare Common Procedure Coding System to comply with Health Insurance Portability and Accountability Act requirements. The home test kit shall be sent by the enrolled Family PACT provider to a Medi-Cal-enrolled laboratory with fee based on Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule.

(9) In order to maximize the availability of federal financial participation under this subdivision, the director shall have the discretion to implement the Family PACT successor state plan amendment retroactively to July 1, 2010.

[Sections (ab) – (af) remain unchanged.]

SEC. 4. 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 literature review conducted for this report. A discussion of CHBRP's system for medical effectiveness grading evidence, as well as lists of MeSH Terms, publication types, and keywords, follows.

Studies of the clinical effectiveness of the HPV vaccine were identified through searches of PubMed, Business Source Complete, CINAHL Complete, Cochrane Library, EconLit, Medline Complete, PsycInfo, Scopus, Web of Science Core Collection. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the 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. The search was limited to studies published from 2012 to present.

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.

Medical Effectiveness Review

The medical effectiveness literature review returned abstracts for 419 articles, of which 52 were reviewed for inclusion in this report. A total of 28 studies were included in the medical effectiveness review for AB 2516.

Medical Effectiveness 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*.[49] 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;*
- *Preponderance of evidence;*
- *Limited evidence;*
- *Inconclusive evidence;* and
- *Insufficient evidence.*

[49] Available at: http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

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)

Adenocarcinoma in Situ
Adverse Effects
Alphapapillomavirus
Anal Cancer
Anal Neoplasms
Anogenital Lesions
Anogenital Warts
Barriers
Cervical Intraepithelial Neoplasia
Completion
Condylomata Acuminata
Drug Utilization
Drug Utilization Review
Effectiveness
Efficacy
Gardasil
Genital Lesions
Genital Warts
Genitourinary Cancer
Genito-urinary Cancer
Genitourinary Neoplasms
Genito-urinary Neoplasms
HPV Cervical Intraepithelial Neoplasia
HPV Infection
HPV Precancerous
HPV Vaccine
HRQOL
Human Papillomavirus
Human Papillomavirus infections
Human Papillomavirus Recombinant Vaccine Quadrivalent, Types 6, 11, 16, 18
Human Papillomavirus Vaccine
Initiation
Intraepithelial Adenocarcinoma
Long Term
Longterm
Oropharyngeal Neoplasms
Papillomavirus Infections
Patient Acceptance of Health Care
Penile Cancer
Penile Neoplasms
Precancerous
Pre-Cancerous
Preinvasive Adenocarcinoma
Prevention
QOL
Quality of Life
Real-World Data
Real-World Evidence
Seropositivity
Side Effects
Uptake
Urogenital Cancer
Urogential Neoplasms
Utilization
Vaccination Coverage
Vaginal Cancer
Vaginal Neoplasms
Venereal Lesions
Venereal Warts
Vulvar Cancer
Vulvar Neoplasms

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

With the assistance of CHBRP's contracted actuarial firm, Milliman, Inc, the cost analysis presented in this report was prepared by the faculty and researchers connected to CHBRP's Task Force with expertise in health economics.[50] 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.[51]

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

Analysis-Specific Data Sources

Current coverage of HPV vaccination with cost sharing for commercial enrollees was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represent 74% of commercial enrollees with health insurance that can be subject to state benefit mandates. In addition, CalPERS, DHCS, and the four largest (by enrollment) DMHC-regulated plans enrolling Medi-Cal beneficiaries were queried regarding related benefit coverage.

For AB 2516, CHBRP used Milliman's Consolidated Health Cost Guidelines Sources Database of California commercial and Medi-Cal claims incurred in calendar year 2019 and 2020. Two years of claims data was used to analyze the impact of COVID-19 and emerging experience related to HPV vaccine utilization among individuals aged 27 to 45 years.

For this analysis, CHBRP relied on CPT® codes to identify services related to AB 2516.[52] Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. CPT is a registered trademark of the American Medical Association.

CHBRP's analysis involved claims data related to HPV vaccine utilization, identified using the following CPT codes:

CPT Code	Description
90649	4vhpv vaccine 3 dose im
90650	2vhpv vaccine 3 dose im
90651	9vhpv vaccine 2/3 dose im

[50] CHBRP's authorizing statute, available at https://chbrp.org/about_chbrp/index.php, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
[51] See method documents posted at http://chbrp.com/analysis_methodology/cost_impact_analysis.php; in particular, see *2023 Cost Analyses: Data Sources, Caveats, and Assumptions*.
[52] CPT copyright 2022 American Medical Association. All rights reserved.

Analysis-Specific Caveats and Assumptions

The analytic approach and key assumptions are determined by the subject matter and language of the bill being analyzed by CHBRP. As a result, analytic approaches may differ between topically similar analyses, and therefore the approach and findings may not be directly comparable.

Assumptions for Baseline Benefit Coverage

- The population subject to the mandated coverage includes individuals covered by DMHC-regulated commercial insurance plans, CDI-regulated policies, CalPERS plans subject to the requirements of the Knox-Keene Health Care Service Plan Act, and DMHC-regulated Medi-Cal plans.
- The responses received to CHBRP's bill-specific survey indicate that over 95% of individuals enrolled in a commercial health plan have coverage for the HPV vaccine with zero cost sharing; 100% of individuals enrolled in a Medi-Cal managed care plan have coverage for the HPV vaccine with zero cost sharing; and 100% of individuals enrolled in a CalPERS plan have coverage for the HPV vaccine with zero cost sharing.

Assumptions for Baseline Utilization, Cost, and Cost Sharing

- The baseline utilization rate, cost per unit, and cost sharing per unit were determined using observed rates in 2020 commercial and Medi-Cal claims data. The observed utilization rate in 2020 was adjusted for the impact of COVID-19 by comparing to the 2019 utilization rate trended to 2020. The adjusted utilization rate in 2020 was trended to 2023 and 2024 using an annual trend of 1%.
- Some cost sharing was observed in 2020 commercial claims data. The average cost sharing per unit in 2020 claims data was trended to 2023 and 2024 using an annual trend of 5%. The assumed baseline average cost sharing per unit did not vary among various group sizes and product types (e.g., grandfathered, nongrandfathered).
- The analysis of AB 2516 presents utilization of HPV vaccine shots per 1,000 enrollees. Because the vaccine shots to complete the vaccination series may occur over multiple plan years, CHBRP is unable to present utilization of HPV vaccinations by series rates. As a result, should enrollees receive two or three doses within the same plan year, they would be counted twice in the data.

Assumptions for Postmandate Utilization, Cost, and Cost Sharing

- The baseline utilization rates for enrollees with zero cost sharing benefit and for enrollees with non-zero cost sharing benefit were compared to determine possible increase in postmandate utilization rate. Commercial enrollees aged 9 to 26 years with zero cost sharing benefit showed greater utilization rate than commercial enrollees aged 9 to 26 years with non-zero cost sharing did. The postmandate utilization rate for the commercial enrollees aged 9 to 26 years with non-zero cost sharing was assumed to be identical to the utilization rate for the commercial enrollees aged 9 to 26 years with zero cost sharing. A similar relationship in utilization rates was not observed for commercial enrollees aged 27 to 45 years. No change in utilization rate was assumed for commercial enrollees aged 27 to 45 years postmandate.
- The postmandate cost per unit was assumed to be identical to the baseline cost per unit.
- The postmandate cost sharing per unit was assumed to be zero.

Determining Public Demand for the Proposed Mandate

CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

- Considers the bargaining history of organized labor; and

- 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 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 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 2615 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 2615 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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CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM COMMITTEES AND STAFF

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.

Faculty Task Force

Paul Brown, PhD, University of California, Merced
Timothy T. Brown, PhD, University of California, Berkeley
Janet Coffman, MA, MPP, PhD, *Vice Chair for Medical Effectiveness*, University of California, San Francisco
Todd Gilmer, PhD, University of California, San Diego
Sylvia Guendelman, PhD, LCSW, University of California, Berkeley
Elizabeth Magnan, MD, PhD, *Co-Vice Chair for Public Health*, University of California, Davis
Sara McMenamin, PhD, *Vice Chair for Medical Effectiveness and Public Health*, University of California, San Diego
Joy Melnikow, MD, MPH, *Co-Vice Chair for Public Health*, University of California, Davis
Aimee Moulin, MD, University of California, Davis
Jack Needleman, PhD, University of California, Los Angeles
Mark A. Peterson, PhD, University of California, Los Angeles
Nadereh Pourat, PhD, *Vice Chair for Cost*, University of California, Los Angeles
Dylan Roby, PhD, University of California, Irvine
Marilyn Stebbins, PharmD, University of California, San Francisco

Task Force Contributors

Bethney Bonilla, MA, University of California, Davis
Danielle Casteel, MA, University of California, San Diego
Shana Charles, PhD, MPP, University of California, Los Angeles, and California State University, Fullerton
Margaret Fix, MPH, University of California, San Francisco
Naomi Hillery, MPH, University of California, San Diego
Jeffrey Hoch, PhD, University of California, Davis
Julia Huerta, MPH, University of California, Davis
Michelle Keller, PhD, MPH, University of California, Los Angeles
Jacqueline Miller, University of California, San Francisco
Marykate Miller, MS, University of California, Davis
Amy Quan, University of California, San Francisco
Dominique Ritley, MPH, University of California, Davis
Emily Shen, University of California, San Francisco
Riti Shimkhada, PhD, University of California, Los Angeles

National Advisory Council

CHBRP Staff

California Health Benefits Review Program
MC 3116
Berkeley, CA 94720-3116
info@chbrp.org
(510) 664-5306

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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.

Garen Corbett, MS
Director

Please direct any questions concerning this document to: California Health Benefits Review Program; MC 3116; Berkeley, CA 94720-3116, info@chbrp.org, or www.chbrp.org