California Health Benefits Review Program

Analysis of California Assembly Bill 2204
Sexually Transmitted Diseases

A Report to the 2019–2020 California State Legislature

April 14, 2020

CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Key Findings

Analysis of California Assembly Bill 2204
Sexually Transmitted Diseases

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

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

AT A GLANCE

For commercial/CalPERS enrollees in plans and policies regulated by Department of Managed Health Care (DMHC) or California Department of Insurance (CDI), the version of California Assembly Bill 2204 analyzed by CHBRP would require coverage of sexually transmitted disease (STD) services provided by out-of-network clinics that receive state/county funds for STD services to be reimbursed at in-network rates and subject only to in-network cost sharing.

1. CHBRP estimates that, in 2020, of the 21.7 million Californians enrolled in state-regulated health insurance, 13.4 million will have insurance subject to AB 2204.
2. Benefit coverage. At baseline, 28% of commercial/CalPERS enrollees have coverage for out-of-network clinics at out-of-network reimbursement and cost-sharing and 72% have coverage that generally limits out-of-network services to emergency or out-of-area situations. Postmandate, 100% would have AB 2204 compliant coverage.
3. Utilization. Postmandate, 38,581 commercial/CalPERS enrollees will shift from in-network providers to out-of-network clinics and 45,558 more will access STD testing and treatment at those out-of-network clinics.
4. Expenditures. Expenditures would increase by $9,668,000 (0.0074%).
5. Medical effectiveness. There is clear and convincing evidence that: (1) the recommended tests and treatments effectively cure or manage STDs; (2) if left untreated, STDs can lead to serious health complications; and (3) treatment of STDs reduces transmission.
6. Public health. Cure or management of STDs would lead to better health outcomes as well as reduced transmission, less premature death, and reduced economic loss.

CONTEXT[1]

Sexually transmitted diseases (STDs) are caused by a pathogen (e.g., bacterium, virus, or other microorganism) transmitted via direct sexual contact with an infected partner. Timely testing and treating of STDs improves health outcomes and reduces transmission to noninfected partners.

For the four STDs with required reporting to the Centers for Disease Control and Prevention (CDC), California is among the highest for chlamydia (13th), gonorrhea (14th), adult syphilis (3rd), and congenital syphilis (5th). Other STDs prevalent in California include herpes, human papillomavirus (HPV), hepatitis B, and human immunodeficiency virus (HIV).

Californians may obtain STD screening, testing, and treatment from a variety of locations and settings throughout the state, some of which receive state/county funds to support STD testing and treatment.

The 13.4 million commercial/CalPERS enrollees in plans and policies regulated by the Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI) have varied coverage for STD services when provided by a clinic that is out-of-network for the enrollee's plan or policy:

- 0% have coverage that reimburses out-of-network clinics at in-network rates with in-network cost sharing.
- 28% have coverage that reimburses out-of-network clinics at currently established out-of-network rates with out-of-network cost sharing.
- 72% have coverage that generally only reimburses out-of-network clinics under emergency circumstances or when the enrollee is out-of-area for all in-network providers.

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

Medi-Cal beneficiaries enrolled in DMHC-regulated plans[2] have coverage for STD services at out-of-network clinics at Medi-Cal fee-for-service rates.

BILL SUMMARY

AB 2204 would define a list of STDs and a list of relevant tests and treatments by reference to the 2015 CDC STD guidelines issued, which were reviewed and reaffirmed in 2019.

For the identified tests and treatments, AB 2204 would require group and individual plans and policies regulated by DMHC and CDI to cover STD services when provided by "noncontracting health facilities." AB 2204 would require and that these facilities be reimbursed at in-network rates; and would require that enrollees pay only in-network cost-sharing rates.

AB 2204 references licensed noncontracting (with the particular health plan or insurer) health facilities that are contractors with the state or county to provide clinical STD services. In this analysis, these will be referred to as "clinics with state/county STD contracts."

Because AB 2204 specifies "group and individual" plans and polices, the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans would not be subject to AB 2204's requirements.[3]

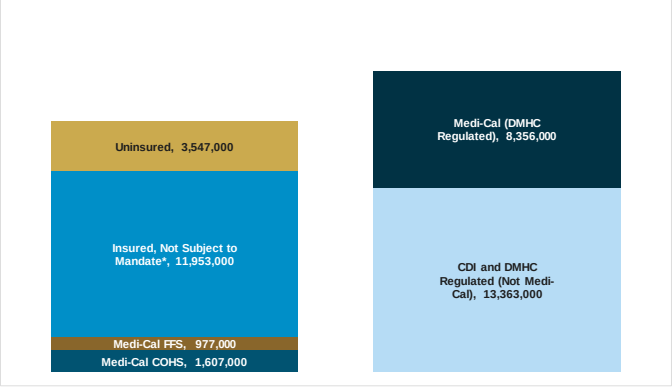
In order to analyze the impacts of AB 2204, CHBRP has made several analytic assumptions, including the following:

- Because AB 2204 specifies testing and treatment for STDs, CHBRP has assumed that AB 2204 would not impact coverage for prevention services, such as the human papillomavirus (HPV) vaccine or pre-exposure prophylaxis (PReP) or post-exposure prophylaxis (PEP) antiretroviral medications (ARVs) for human immunodeficiency virus (HIV).
- Because AB 2204 specifies tests and treatments related to STDs, CHBRP has assumed that the bill would affect coverage for tests and treatments related to the disease, and would not be relevant to tests and treatment related to further complications (such as the opportunistic infections that may occur among HIV-positive persons).
- Because AB 2204 specifies the CDC's STD guidelines, which focus on early tests and treatments, CHBRP has assumed that AB 2204 would not affect coverage for services that may be relevant later in a disease progression (such as hospitalization for hepatitis).

If any of the assumptions listed above is incorrect, the impact of the bill could be greater by orders of magnitude.

Additionally, AB 2204 specifies that its benefit coverage requirements are applicable to out-of-network services provided by clinics with state/county STD funds. A variety of federal, state, and county funds support STD testing and treatment. At the state level (but sometimes with federal support), sources range from fee-for-service reimbursement by the state's Family PACT program to county establishment of public STD clinics. The clinics referenced by AB 2204 may also access federal funding, such as the Human Resources Service Agency's reduced drug costs program or (through state or local health departments) STD control funds from the Centers for Disease Control. Given the variety of funding sources available, and the variation of sources to which particular clinics may be attached, CHBRP cannot ascertain the number of such clinics that would be affected by AB 2204, but has assumed those that exist would be able to absorb the extra utilization that could be the result of passage of AB 2204 into law.

Figure A. Health Insurance in CA and AB 2204



Source: California Health Benefits Review Program, 2020.
Notes: * Medicare beneficiaries, enrollees in self-insured products, etc.

[2] As do those enrolled in County Organized Health System managed care programs and those in the fee-for-service program.

[3] Personal communication, W. White, California Department of Health Care Services, March 2020.

IMPACTS

Medical Effectiveness

The CDC STD Treatment Guidelines referenced by AB 2204 are the undisputed standard of care for the testing and treatment of STDs. These guidelines present *clear and convincing* evidence that:

- The recommended tests and treatments effectively cure or manage the listed STDs;
- Untreated, the listed STDs can lead to serious health complications; and
- Treatment of the listed STDs reduces transmission.

Benefit Coverage, Utilization, and Cost

As noted above, baseline benefit coverage varies for commercial/CalPERS enrollees. Postmandate, 100% would have benefit coverage that includes in-network cost sharing and reimbursement for STD tests and treatments provided by some out-of-network clinics (those receiving state/county STD funds). Almost all — over 94% — commercial/CalPERS enrollees have a pharmacy benefit regulated by DMHC or CDI that covers both generic and brand-name outpatient prescription medications. Though such enrollees would still have no pharmacy benefit when receiving care from an in-network provider, they would gain benefit coverage from AB 2204 for outpatient medications for STDs when accessed through some out-of-network clinics. Although CHBRP cannot estimate the amount, there would be some additional administrative costs for those plans and policies (to create outpatient medication coverage applicable only when accessed through some out-of-network clinics).

Utilization

AB 2204 will lead to an overall increase of STD services driven by reducing cost sharing for enrollees as well as increasing funding for such services at some STD clinics (those with state/county STD funding). Additionally, because STD services will have lower cost sharing at a broader range of locations, it will be more convenient for many enrollees to receive such services.

Antiretroviral medications as treatment (not prevention) for HIV-positive enrollees are included in this analysis. Because these medications have a very different utilization pattern (lifetime use, rather than the more common single-filled prescription) and much higher unit cost (average of $1,965 for a 1-month supply), they are presented separately from the other STD services.

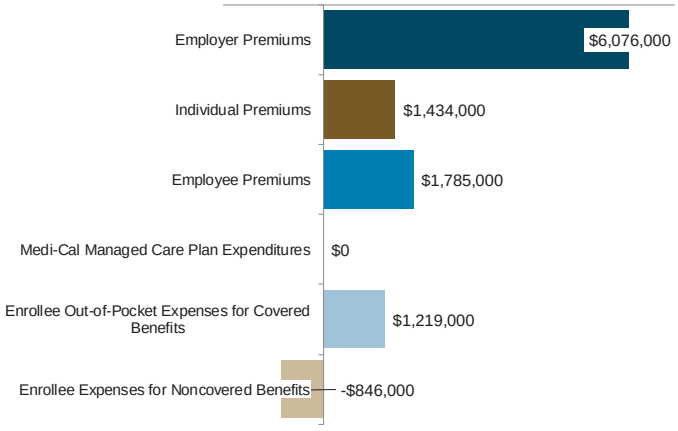
At baseline, 24,951 HIV-positive commercial/CalPERS enrollees use HIV medications received from an in-network provider. Given the high unit costs and the higher applicable cost sharing, no measurable number of enrollees are estimated to use out-of-network providers or to self-pay for these medications. Postmandate, an estimated 749 enrollees would shift to using some out-of-network STD clinics for accessing their HIV medications.

For other tests and treatments related to common STDs (including office visits, diagnostic tests, antibiotic prescriptions, and minor surgeries), CHBRP estimates that currently, 1,286,605 commercial/CalPERS enrollees use in-network providers, 80,164 enrollees use out-of-network clinics covered by insurance, and 428,868 enrollees self-pay. Commercial/CalPERS enrollees (and others) commonly choose to conceal their insurance status and self-pay for STD tests and treatments due to privacy concerns, particularly in relation to other family members that may share their health insurance. Postmandate, 86,819 more enrollees will use STD services at some out-of-network STD clinics. CHBRP also projects a decrease in the use of in-network providers for STD services by 38,581, as people shift to using STD clinics now that the cost sharing would be the same. There will with a smaller decrease of 2,680 enrollees using services at an out-of-network STD clinic through self-pay.

Expenditures

As noted in Figure B, for all enrollees in plans and policies regulated by DMHC and CDI, AB 2204 would increase expenditures by $9,668,000 (0.0074%).

Figure B. Expenditure Impacts of AB 2204



Source: California Health Benefits Review Program, 2020.

Medi-Cal

As noted above, the structure of the mandate in AB 2204 exempts from compliance the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans, so it would not impact Medi-Cal.

CalPERS

For CalPERS, AB 2204 would increase premium expenditures by $1,785,000 (0.0112%).

Number of Uninsured in California

Because the expenditure impact is less than 1%, no measureable impact on the number of uninsured is projected.

Public Health

In the first postmandate year, an additional 45,558 commercial/CalPERS enrollees with newly compliant benefit coverage would seek medically effective testing and treatment for STDs.

Testing and treatments for STDs recommended by the CDC promote:

- Infection cure rates of 92% to 100% based on the type of STD (e.g., chlamydia cure rates of 97% to 98%);
- Viral replication suppression — leading to reduction, elimination, and/or shortened duration of related symptoms as well as decreased infectiousness; and
- Reduced transmission to noninfected persons.

Given the anticipated increase in utilization, there will be an increase in the number of individuals tested, diagnosed, and treated for STDs, and subsequent decreases in undesirable short- and long-term health outcomes.

Long-Term Impacts

Over the long term, increases in STD tests and treatments are known to improve a person's health and to reduce the spread of STDs throughout the population.

Such increases can:

- Improve related long-term outcomes. For example, a reduction in the prevalence of syphilis can lead to a reduction in congenital syphilis (transmitted from mother to child at birth), which can mean a reduction in adverse health outcomes among both mother and infant.
- Reduce premature death, a result clearly related to congenital syphilis, HPV-related cancers, hepatitis B, and HIV.
- Reduce economic loss (consisting of direct medical costs as well as the indirect costs related to a reduction in productivity due to premature mortality):
    - For each case of syphilis, approximately $734 in direct and $144 in indirect costs would be avoided per individual case prevented.
    - For each case of congenital syphilis, approximately $8,6146 in direct and $77,526 in indirect costs would be avoided per individual case prevented.
    - For each case of gonorrhea, approximately $440 in direct and $219 in indirect costs would be avoided per individual case prevented among females.
    - For each case of chlamydia, approximately $404 in direct and $190 in indirect costs would be avoided per individual case prevented among females.
    - For each case of HIV, approximately $250,000 in direct and $1.1 million in indirect costs would be avoided per individual case prevented.

Essential Health Benefits and the Affordable Care Act

AB 2204 would alter the terms and conditions of existing benefit coverage, but would not require coverage for a new benefit and so appears unlikely to exceed the definition of essential health benefits in California.

At the time of this CHBRP analysis, there is substantial uncertainty regarding the impact of the COVID-19 pandemic on premium rates and health plan enrollment, including how the pandemic will impact healthcare costs in 2021. Because the variance of potential outcomes is significant, CHBRP does not take these effects into account as any projections at this point would be speculative, subject to federal and state decisions and guidance currently being developed and released. In addition, insurers', providers', and consumers' responses are uncertain and rapidly evolving to the public health emergency and market dynamics.

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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. AB 2204 Impacts on Benefit Coverage, Utilization, and Cost, 2021

	Baseline (2021)	Postmandate Year 1 (2021)	Increase/ Decrease	Change Postmandate
Benefit coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	21,719,000	21,719,000	0	0.00%
Total enrollees with health insurance subject to AB 2204	13,363,000	13,363,000	0	0.00%
Number of commercial/CalPERS enrollees with:				
Out-of-network STD coverage at in-network cost sharing/reimbursement	0	13,363,000	13,363,000	100%
Out-of-network STD coverage without in-network cost sharing/reimbursement	3,744,000	0	−3,744,000	−100.00%
Only in-network coverage for STD services	9,619,000	0	−9,619,000	−100.00%
Percent of commercial/CalPERS enrollees with:				
Out-of-network STD coverage at in-network cost sharing/reimbursement	0.00%	100.00%	100%	100%
Out-of-network STD coverage without in-network cost sharing/reimbursement	28%	0.00%	−100%	−100%
Only in-network coverage for STD services	72%	0.00%	−100%	−100%
Utilization and cost				
Number of commercial/CalPERS enrollees utilizing:				
HIV medications (antiretrovirals)				
From an in-network provider	24,951	24,202	(749)	−3.00%
From an out-of-network provider	0	749	749	—
Self-pay (e)	0	—	—	0.00%
Other STD-related services				
From an in-network provider	1,286,605	1,248,025	(38,581)	−3.00%
From an out-of-network provider	80,164	166,983	86,819	108.30%
Self-pay	428,868	426,188	(2,680)	−0.62%
Average unit costs				
HIV medications (per monthly fill)				
From an in-network provider	$1,965	$1,965	$0.00	0.00%
From an out-of-network provider (f)	—	$1,965	—	—
Self-pay (e)	—	—	—	—
Other STD services				
From an in-network provider	$63	$63	$0.00	0.00%
From an out-of-network provider (g)	$43	$46	$2.97	6.87%
Self-pay	$61	$61	$0.00	0.00%

Expenditures				
Premium (expenditures) by payer				
Private employers for group insurance	$54,037,059,000	$54,042,803,000	$5,744,000	0.0106%
CalPERS HMO employer expenditures (b) (c)	$3,264,098,000	$3,264,430,000	$332,000	0.0102%
Medi-Cal Managed Care Plan expenditures	$29,218,820,000	$29,218,820,000	$0	0.0000%
Enrollee premiums (expenditures)				
Enrollees for individually purchased insurance	$15,689,758,000	$15,691,192,000	$1,434,000	0.0091%
Individually purchased – outside exchange	$4,412,875,000	$4,413,241,000	$366,000	0.0083%
Individually purchased – Covered California	$11,276,883,000	$11,277,951,000	$1,068,000	0.0095%
Enrollees with group insurance, CalPERS HMOs, Covered California, and Medi-Cal Managed Care (c)	$15,867,227,000	$15,869,012,000	$1,785,000	0.0112%
Enrollee out-of-pocket expenses				
For covered benefits (deductibles, copayments, etc.)	$12,776,801,000	$12,778,020,000	$1,219,000	0.0095%
For noncovered benefits (d)	$135,333,000	$134,487,000	−$846,000	−0.6251%
Total expenditures	$130,989,096,000	$130,998,764,000	$9,668,000	0.0074%

Source: California Health Benefits Review Program, 2020.

Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.[4]

(b) Approximately 57.36% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five (20.5%) of these enrollees has a pharmacy benefit not subject to DMHC.[5] CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

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

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

(e) Although convenience and speed will encourage some such for other, lower unit cost STD medications, due to the high unit cost per monthly filled prescription and the resulting high annual unit cost, CHBRP estimates no measurable baseline self-pay for HIV medications.

(f) Although there may be some payments to out-of-network pharmacies for other, lower–unit-cost STD medications, due to the high unit cost per monthly filled prescription and the resulting high annual unit cost, CHBRP estimates no measurable baseline payments by plans or insurers to out-of-network pharmacies for HIV medications.

(g) Only services provided by out-of-network clinics with state/county STD funding will be reimbursed at in-network rates, postmandate. Other out-of-network clinics or other types of out-of-network providers will continue to be reimbursed at the out-of-network rates. Therefore, the average would rise, but would not equal the in-network rate.

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

[4] For more detail, see *Estimates of Sources of Health Insurance in California for 2021*, available at http://chbrp.org/other_publications/index.php.
[5] For more detail, see *Estimates of Pharmacy Benefit Coverage in California for 2021*, available at http://chbrp.org/other_publications/index.php.

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)[6] conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 2204, Sexually Transmitted Diseases (STDs).

AB 2204 would define a list of STDs and a list of relevant tests and treatments by reference to the CDC's guidelines. CHBRP uses the most current set of those guidelines (CDC, 2015) as the basis for this analysis.

For the identified tests and treatments (see Table 3 in the *Medical Effectiveness* section), AB 2204 would require group and individual plans and policies regulated by the Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI) to cover services when provided by "noncontracting health facilities" and

- Would require that these facilities be reimbursed at in-network rates; and
- Would require that enrollees pay only in-network cost-sharing rates.

AB 2204 references licensed noncontracting (with the particular health plan or insurer) health facilities that are contractors with the state or county to provide clinical STD services. In this analysis, these will be referred to as "clinics with state/county STD contracts."

As AB 2204 specifies "group and individual" plans and polices, the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans would not be subject to AB 2204's requirements.[7]

The full text of AB 2204 can be found in Appendix A.

Relevant Populations

If enacted, AB 2204 would affect the health insurance of approximately 13.4 million enrollees (34% of all Californians). This represents 62% of the 21.7 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law — health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). If enacted, the law would affect the health insurance of commercial/CalPERS enrollees in DMHC-regulated plans and CDI-regulated policies, exempting the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

Analytic Approach and Key Assumptions

As AB 2204 specifies testing and treatment for STDs, CHBRP has assumed that AB 2204 would not impact coverage for prevention services, such as the Human papillomavirus (HPV) vaccine or pre-exposure prophylaxis (PReP) or post-exposure prophylaxis (PEP) antiretroviral medications (ARVs) for human immunodeficiency virus (HIV).

As AB 2204 specifies tests and treatments related to STDs, CHBRP has assumed that the bill would affect coverage for tests and treatments related to the disease, and would not be relevant to tests and treatment related to further complications (such as the opportunistic infections that may occur among HIV-positive persons).

[6] CHBRP's authorizing statute is available at www.chbrp.org/faqs.php.
[7] Personal communication, W. White, California Department of Health Care Services, March 2020.

As AB 2204 specifies the CDC's STD guidelines, which focus on early tests and treatments, CHBRP has assumed that AB 2204 would not affect coverage for services that may be relevant later in a disease progression (such as hospitalization for Hepatitis).

If any of the assumptions listed above is incorrect, in particular, if the bill impacted additional coverage, such as hospitalization for hepatitis, treatments for the opportunistic infections related to HIV, or HIV preventive (PReP or PEP) use of HIV antiretroviral medications, the impact of the bill would be greater by orders of magnitude.

AB 2204 specifies that its benefit coverage requirements are applicable to out-of-network services provided by clinics with state/county STD funds. A variety of federal, state, and county funds support STD testing and treatment. At the state level (but sometimes with federal support) sources range from fee-for-service reimbursement by the state's Family PACT program (DHCS, 2020) to the county establishment of public STD clinics, such as San Francisco's City Clinic (SFCC, 2020). The clinics referenced by AB 2204 may also access federal funding, such as the Human Resources Service Agency's reduced drug costs program (HRSA, 2020) or (through state or local health departments) STD control funds from the Centers for Disease Control and Prevention (KFF, 2020). Given the variety of funding sources available, and the variation of sources to which particular clinics may be attached, CHBRP cannot ascertain the number of such clinics that would be affected by AB 2204, but has assumed that those that exist would be able to absorb the extra utilization that could be the result of passage of AB 2204 into law.

Interaction With Existing Requirements

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

California Policy Landscape

California law and regulations

Current law[8] requires and current boiler plate contract language[9] specifies that DMHC-regulated plans and County Organized Health System (COHS) managed care plans enrolling Medi-Cal beneficiaries cover STD services provided by out-of-network providers at Medi-Cal's applicable fee for service rate.

Similar requirements in other states

CHBRP is unaware of similar requirements in other states being applicable to the benefit coverage of enrollees in commercial health insurance.

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 2204 may interact with requirements of the ACA as presently

[8] Welfare and Institutions Code 14132.07.
[9] See the Two Plan Model Boiler Plate Contract, available at https://www.dhcs.ca.gov/provgovpart/Documents/Two-PlanCCIFinalRuleBoilerplate.pdf.

exists in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).[10,11]

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

Essential Health Benefits

Nongrandfathered plans and policies sold in the individual and small-group markets are required to meet a minimum standard of benefits as defined by the ACA as essential health benefits (EHBs). In California, EHBs are related to the benefit coverage available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.[12,13] CHBRP estimates that approximately 4 million Californians (10%) have insurance coverage subject to EHBs in 2021.[14]

States may require plans and policies to offer benefits that exceed EHBs.[15] However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the qualified health plan.[16,17] Health plans and policies sold outside of the health insurance marketplaces are not subject to this requirement to defray the costs. State rules related to provider types, cost sharing, or reimbursement methods would not meet the definition of state benefit mandates that could exceed EHBs.[18]

AB 2204 would alter provider reimbursement and cost sharing, but would not require coverage for a new benefit and so appears not to exceed the definition of EHBs in California.

Federally Selected Preventive Services

As soon as 12 months after a recommendation appears in any of several listed sources,[19] the ACA requires that nongrandfathered group and individual health insurance plans and policies cover certain services, including some STD testing and treatments, without cost sharing when delivered by in-network providers.

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[10] 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.
[11] 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.
[12] CCIIO, Information on Essential Health Benefits (EHB) Benchmark Plans. Available at: https://www.cms.gov/cciio/resources/data-resources/ehb.html.
[13] H&SC Section 1367.005; IC Section 10112.27.
[14] CHBRP, *Estimates of Sources of Health Insurance in California in 2021*. Available at: www.chbrp.org/other_publications/index.php.
[15] ACA Section 1311(d)(3).
[16] State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: https://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.
[17] However, as laid out in the Final Rule on EHBs HHS released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the state's EHBs, and there would be no requirement that the state defray the costs of those state-mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.
[18] Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.
[19] More information is available on CHBRP's website under "Resources": www.chbrp.org/other_publications/index.php.

As noted in Table 3 in the *Medical Effectiveness* section, in some cases, principally for pregnant enrollees, the Federally Selected Preventive Services mandate[20] would be stricter than AB 2204, prohibiting all cost sharing for some STD tests and treatments for some enrollees.

At the time of this CHBRP analysis, there is substantial uncertainty regarding the impact of the COVID-19 pandemic on premium rates and health plan enrollment, including how the pandemic will impact healthcare costs in 2021. Because the variance of potential outcomes is significant, CHBRP does not take these effects into account as any projections at this point would be speculative, subject to federal and state decisions and guidance currently being developed and released. In addition, insurers', providers', and consumers' responses are uncertain and rapidly evolving to the public health emergency and market dynamics.

[20] See CHBRP's *Federal Preventive Services Mandate and California Mandates*, available at http://chbrp.org/other_publications/index.php#revize_document_center_rz44.

BACKGROUND ON SEXUALLY TRANSMITTED DISEASES

AB 2204 would alter requirements related to coverage of identified tests and treatments for sexually transmitted diseases (STDs when provided by "noncontracting health facilities." AB 2204 would define the list of STDs and the relevant tests and treatments through reference to the 2015 guidelines published by the Centers for Disease Control and Prevention (CDC, 2015). AB 2204 would require group and individual plans and policies regulated by the Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI) to reimburse STD-related testing and treatment provided by noncontracting health facilities at in-network rates. AB 2204 would also require that enrollees be responsible only for in-network cost sharing. This background section provides information related to sexually transmitted diseases (STDs) to provide context for the consideration of the *Medical Effectiveness, Benefit Coverage, Utilization, and Cost Impacts, and Public Health Impacts* sections. Descriptions of each specific STD is discussed along with testing, treatment, and outcomes in the *Medical Effectiveness* section, whereas this section provides a background on STDs in general incidence and prevalence rates for individual STDs. Note: throughout this report, the term *STDs* will be inclusive of the following STDs, unless otherwise delineated: (1) bacterial vaginosis; (2) chlamydia; (3) genital herpes simplex; (4) gonorrhea; (5) hepatitis B;[21] (6) HIV; (7) human papillomavirus; (7) pediculosis pubis; (10) scabies; and (11) trichomoniasis.

Sexually Transmitted Diseases

Sexually transmitted diseases (STDs) are defined as a type of disease or infection caused by a pathogen (e.g., bacterium, virus, or other microorganism) that can be transmitted or acquired via direct sexual contact from person to person (CDC, 2015). Obtaining testing and treatment for STDs in a timely manner are key to limiting adverse health outcomes and to reducing the transmission of disease to noninfected partners.

Based on the pathogen, STDs can be categorized into four classes of diseases, including: (1) bacterial; (2) viral; (3) ectoparasitic (i.e., infection caused by a parasite); and (4) protozoal. Treatments vary by class of disease and are described in complete detail in the *Medical Effectiveness* section. The list of STDs relevant to our analysis are listed in Table 2.

Note: STD-specific descriptions and summaries, as well as their tests and treatments are described in further detail in the *Medical Effectiveness* section. This section focuses on the incidence and prevalence of the STDs relevant to this analysis.

STD Prevalence in California

The following table (Table 1) identifies the 2018 prevalence rates for the most common STDs among those referenced in the 2015 CDC Treatment Guidelines. Four STDs are required to be reported to the CDC by state public health departments: chlamydia, gonorrhea, syphilis, and chancroid (CDC, 2019). Chancroid is extremely rare with three cases in 2018, one being in California, and thus it was excluded from the table below (CDC, 2019). Based on 2018 CDC STD reporting surveillance data, California ranks among the top states for highest rates of chlamydia (13th), gonorrhea (14th), adult syphilis (3rd), and congenital syphilis (5th) among all states (CDC, 2019). All other STDs listed below are not required to be

[21] Hepatitis A and hepatitis C are not included in this CHBRP analysis. Hepatitis A is an acute virus that is primarily transmitted by the fecal–oral route via person-to-person contact or through consumption of tainted water or food. Although hepatitis A can be transmitted via sexual activity, the main method of transmission is through the fecal–oral route; therefore; CHBRP is not including an evaluation of hepatitis A. Hepatitis C is a chronic virus that is primarily transmitted through use of shared drug-injection needles and related paraphernalia. Although hepatitis C is transmissible through sexual contact, studies have demonstrated that transmission through sexual activity is largely inefficient; therefore, CHBRP is not evaluating hepatitis C. Furthermore, treatment for hepatitis C is not specified in the 2015 CDC Treatment Guidelines.

reported either at the state or federal level and the prevalence rates were gathered from a variety of sources.

Table 2. Prevalence/Incidence of Selected STDs in California, 2018

	Prevalence/Incidence Rate	Number of Cases
Bacterial	**Rate (per 100,000 population)**	**Cases**
Bacterial vaginosis (a)	6,813 per 100,000	2,712, 787
Chlamydial infections (b)	583.0 per 100,000*	232,181
Gonococcal infections (b)	199.4 per 100,000*	79,397
Syphilis (b)	62.8 per 100,000*	25,015
Congenital	68.2 per 100,000 live births*	329
Viral		
Genital herpes simplex (HSV-2) (c)	5,410 per 100,000	2,513,970
Hepatitis B (d)	24.8 per 100,000*	9,778
Human immunodeficiency virus (HIV) (e)	342.9 per 100,000	136,566
Human papillomavirus (HPV) (f)	27,122 per 100,000	10,799,238
HPV-associated cancer (g)	10.8 per 100,000 *	4643
Ectoparasitic		
Pediculosis pubis (pubic lice) (h)	638 per 100,000*	254,100
Scabies (i)	152 per 100,000*	61,624
Protozoal		
Trichomoniasis (j)	830 per 100,000	330,330

Sources: California Health Benefits Review Program, 2020 adapted from (a) Koumans et al., 2007; (b) CDPH, 2019a; (c) McQuillan et al., 2018; (d) CDPH, 2018b; (e) CDPH, 2018a; (f) McQuillan et al., 2017; (g) U.S. Cancer Statistics Working Group, 2019; (h) Gewirtzman et al., 2011; (i) adapted from Table 3 and (j) Flagg et al., 2019.

* Indicates Incidence rate.

Other STDs Not Included in CHBRP Analysis

Although also included in the 2015 CDC STDs Treatment Guidelines, 12 STDs have been excluded from CHBRP analysis for reasons such as rarity of disease occurrence within the United States (e.g., granuloma inguinale); alternative methods for disease transmission not exclusively attributed to sexual activity with an infected partner (e.g., hepatitis A is primarily transmitted by the fecal–oral route); and lack of Food and Drug Administration (FDA)-approved diagnostic tests to determine diagnosis (e.g., mycoplasma genitalium). A description of the full rationale for why CHBRP excluded each individual STD is provided in Appendix D.

Prevention, Treatment, and Management of STDs

Per the 2015 CDC STDs Treatment Guidelines, the prevention and control of STDs are guided by five strategic priorities, including:

Prevention:

1. Provision of accurate risk assessment (inclusive of screening), education, and counseling to persons at risk on methods in which to avoid STDs;
2. Provision of vaccinations (i.e., pre-exposure vaccinations) to persons at risk for STDs that can be prevented by vaccine;

Testing and treatment:

3. Identification of infected persons (presenting with symptoms or as asymptomatic) associated with STDS;
4. Effective diagnosis, treatment, counseling, and related case management of infected persons; and

Reduction in transmission:

5. Effective evaluation, treatment, and counseling, and related case management of sex partners of infected persons with an STD.

Prevention of STDs includes provision of an accurate risk assessment to assess behavioral and biological risk for acquiring or transmitting STDs (CDC, 2015). As part of the health care visit, the CDC (2015) recommends that providers routinely obtain sexual history and address risk reduction through the provision of prevention counseling. Per the United States Preventive Services Task Force, high-intensity behavioral counseling is recommended for sexually active adolescents and young adults who are at an increased risk for acquiring STDs (CDC, 2015).

Methods to prevent acquisition or transmission of STDs are broad and diverse and vary in efficacy. These include: pre-exposure vaccinations, abstinence; reduction in the number of concurrent sexual partners at one time; utilization of male or females condoms; utilization of a cervical diaphragm; application of topical microbicides and spermicides; male circumcision; emergency contraception; and/or post-exposure prophylaxis (PEP) for HIV and STDs (CDC, 2015). Use of antiretroviral treatment of persons with HIV to prevent HIV infection in partners has also been demonstrated to decrease the risk of transmission (CDC, 2015).

Testing and treatment specific to acquired STD(s) (relevant to this analysis) will be discussed in the *Medical Effectiveness* section.

Disparities[22] and Social Determinants of Health[23] in STDs

Per statute, CHBRP includes discussion of disparities and social determinants of health (SDoH) as it relates to the STDs. Disparities are differences between groups that are modifiable. SDoH include factors outside of the traditional medical care system that influence health status and health outcomes (e.g., income, education, geography, etc.). CHBRP found literature identifying disparities and SDOH by race/ethnicity, age, gender, sexual orientation, gender identity, incarceration status, socioeconomic status, and stigma.

Race or ethnicity

According to the CDC (2017b), disparities persist among racial and ethnic minorities (including Hispanic groups) related to rates of STDs compared to rates of STDs among Whites within the United States. These disparities cannot be explained by individual or behavioral differences, but rather stem from systemic, societal, and cultural barriers to obtaining STD prevention, screening, and/or treatment services. Furthermore, it's important to note that racial/ethnic differences in STD rates may be undercounted for certain minority groups such as Hispanics as many case reports do not include racial or ethnic data (CDC, 2017b).

Specific to chlamydia, rates increased for all racial and Hispanic ethnic groups from 2013 to 2017, including an increase of 3.7% among American Indians/Alaska Natives; 29.6% among Asian; 6.1% among Blacks, 19.4% among Native Hawaiians/Other Pacific Islanders; 20.2% among Whites; 59.9% among multirace; and 10.5% among Hispanics (CDC, 2017b). In 2017, the rate of reported chlamydia cases among Black women was 5 times the rate of reported cases among White women (or 1,419.9 per 100,000 vs. 283.3 per 100,000, respectively) (CDC, 2017b). Similarly, the rate of reported chlamydia cases among Black men was 6.6 times the rate of reported cases among White men in 2017 (or 907.3 per 100,000 vs. 137.1 per 100,000, respectively) (CDC, 2017b). The rate of reported chlamydia cases among American Indians/Alaska Natives was found to be 3.7 times the rate of among Whites (CDC, 2017b). Native Hawaiians/Other Pacific Islanders had a similar rate, in which the rate of reported chlamydial rates was 3.4 times the rate among Whites, and interestingly, 5.5 times the rate among Asians. Among Hispanics the rate was 1.9 times greater than the rate among Whites (CDC, 2017b).

Similar disparities were found for racial and ethnic minorities related to rates of gonorrhea. For example, in 2017, the rate of reported gonorrhea cases among Blacks was 8.3 times the rate among Whites (or 548.1 per 100,000 vs. 66.4 per 100,000, respectively) (CDC, 2017b). Similar disparities among racial and ethnic minorities across the United States were also found with respect to the rates of primary and secondary syphilis. In 2017, 39.1% of all reported cases of congenital syphilis (i.e., transmission from infected mother to baby) occurred among Black women (or 58.9 per 100,000 live births) (CDC, 2017b). A majority of racial and ethnic minorities (except for Asians/Pacific Islanders) had higher reported rates of congenital syphilis in comparison to Whites.

Age

The rates of STDs among adolescents and young adults suggest that 15- to 24-year-old persons acquire half of all newly diagnosed/reported STDs in the United States (CDC, 2017c). Moreover, 25% of all sexually active adolescent females in the U.S. are diagnosed with an STD, such as chlamydia or HPV (CDC, 2017c). In comparison to older adults, disparities persist among sexually active adolescents (15 to

[22] 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).

[23] 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; Healthy People 2020, 2019)). See CHBRP's SDoH white paper for further information: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

19 years of age) and young adults (20 to 24 years of age) as these individuals may be at higher risk for STD acquisition due to a combination of factors, including behavioral, biological, and cultural reasons (CDC, 2017c). More specifically, factors related to increased risk among adolescents and young adults include: having more than one sexual partner at one time, having sequential sexual partnerships during a condensed period of time, opting out of or failing to use barrier protection appropriately, and facing barriers to accessing primary care services. Moreover, adolescent females may be at higher risk for STD infection due to having increased cervical ectopy (i.e., columnar cells found within the cervical canal) (CDC, 2017c). Despite this being a normal occurrence among adolescent and young adults, these columnar cells—located on the outer surface of the cervix—are more susceptible to infection (CDC, 2017c). According to the CDC, higher rates of STDs among adolescents and young adults may also be a reflection of the multitude of barriers to accessing care, including lack of access to quality STD prevention, treatment, and management services; inability to pay; lack of transportation; long wait times to see a provider; schedule conflicts related to clinic hours of operation and work/school schedules; embarrassment and/or stigma around seeking STD services; method of specimen collection; and confidentiality concerns (CDC, 2017c).

Women and infants

According to the CDC, chlamydia and gonorrhea disproportionately affect women, as women often present as asymptomatic during early infection, leading to the development of more serious health consequences (CDC, 2017d). For example, if left untreated, chlamydial and gonococcal infections may lead to pelvic inflammatory disease (PID)—a very severe disease that can result in infertility and/or ectopic pregnancy among women (CDC, 2017d). PID and tubal factor infertility (as a result of chlamydial or gonococcal infections) data indicate that as much as 10% of untreated chlamydial infections develop into clinically diagnosed PID among women in the United States; and PID risk among women with untreated gonococcal infections may be even higher (CDC, 2017d). Pregnant women are at increased risk for STDs and can experience severe complications due to intrauterine (i.e., within the uterus) or perinatally transmitted (i.e., mother to child transmission) STDs (CDC, 2015). Similar to nonpregnant women, a high proportion of pregnant women diagnosed with chlamydia or gonorrhea present as asymptomatic in the United States (CDC, 2017d). Factors related to increased risk among pregnant women are broad and have the potential to vary by STD. For example, factors related to increased risk for gonorrhea among pregnant women may include: living in a high-morbidity area; prevalence of current or previous coexisting sexually transmitted infections (STI); having multiple concurrent sex partners; and/or opting out of using barrier protection whereas factors related to increased risk of Hepatitis B among pregnant women may also include recent or current injection drug-use (CDC, 2016). If left untreated, STD infections during pregnancy can lead to a number of complications, including premature delivery, premature rupture of the membranes, low birth weight, and/or stillbirth (CDC, 2017d). Additionally, untreated infections can also affect the infant, leading to conjunctivitis infections or pneumonia depending on the type of STD infection (CDC, 2017d).

Sexual orientation

According to the CDC (2017a), disparities exist among gay/homosexual, bisexual, and other men who have sex with men (commonly referred to as men who have sex with men [MSM]) in comparison to women and men who have sex with women. Men who have sex with men (MSM) are defined as a broad and diverse category of men who have varied sexual behaviors, identities, and individualized health care needs (CDC, 2015). Disparities among MSM reflect those observed in the general population, in which STDs disproportionately affect racial minority and Hispanic MSM as well as MSM of lower socioeconomic status, and young MSM (CDC, 2017a). Nationwide, MSM accounted for 68.2% of reported primary and secondary syphilis cases among women or men with information about the sex of their partners in 2017 (CDC, 2017a). The higher burden of STDs of MSM may be indicative of having a broad and diverse sexual network; reduced access to screening, treatment, and management; and/or having differential experiences with stigma and discrimination (CDC, 2017a). Other factors related to increased risk among MSM include: engaging in anal sex, in which the rectal mucosa is highly susceptible to STD pathogens;

having an increased likelihood for substance use; having an increased likelihood for participating in varied and dynamic sexual networks; and having increased rates of practicing unsafe sexual practices.

Women who have sex with women (WSW) are defined as a broad and diverse category of women who have varied sexual behaviors, sexual identities, and individualized health care needs (CDC, 2015). According to the CDC (2015), studies have reported that some WSW, specifically adolescents and young women and women with concurrent female and male sexual partners, are at increased risk for STDs and HIV. Factors related to increased risk among WSW include: having diverse sexual practices; increased risk behaviors; and opting out of using barrier protection such as gloves, condoms, and/or dental dams.

Gender identity

Transgender persons are defined as individuals who identify with a sex that varies from what they were assigned at birth given their anatomy (CDC, 2015). For example, transgender women (also referred to as trans-women or transgender male to female) identify as women despite being assigned as male at birth due their anatomy. Similarly, transgender men (also known as trans-men or transgender female to male) identify as men despite being assigned as female at birth due their anatomy. It's important to note that gender identity is separate from sexual orientation and transgender persons may use varied and fluid terminology to identify themselves throughout their life course (CDC, 2015). Among the few studies reporting on STD prevalence among transgender persons, factors related to increased risk for STDs and HIV include having diverse sexual practices and preferences (such as having sex with men, women, or both at the same time, or identifying as heterosexual, gay, lesbian, queer, or bisexual) and having an increased likelihood of engaging in risky behaviors (CDC, 2015).

Persons in correctional facilities

Multiple studies have reported that incarcerated individuals — especially individuals aged 35 years and younger — are at high risk for STDs, including HIV and viral hepatitis (CDC, 2015). Factors related to increased risk among incarcerated persons include: having an increased association with lower socioeconomic status; and living in urban areas. As reported in Hogben and Leichliter (2008), incarceration can also lead to the disruption of sexual networks and contribute to the maintenance of poverty, thereby leading to further economic disadvantage among individuals living in poverty — which is also known to be associated with STD acquisition.

Socioeconomic status

Socioeconomic status (SES) is defined as an individual's or population's position within a social structure and is typically measured as a combination of education, income, and/or occupation (Winkleby et al., 1992). Studies have indicated an association between low SES and the acquisition of STDs (Dean and Fenton, 2010; Hogben and Leichliter, 2008). Researchers found that a lack of resources and inequality of resource distribution increased the likelihood for risky sexual behavior, lack of access to health care services, as well as increased STD rates. Moreover, poverty and lack of employment were also found to be associated with an increased likelihood for having a broader and more diverse sexual network. For example, researchers found that the migration of black men to the southeastern United States seeking better employment opportunities was associated with increased STD rates—as migration led to a disproportionate sex ratio, in which there were fewer men in the population compared to women. (Hogben and Leichliter, 2008; Kilmarx et al., 1997).

Stigma

According to Dean and Fenton (2010), stigma is also an important social determinant with a direct connection to individual health-seeking behaviors as well as the control and maintenance of diseases such as STDs. Given the role that stigma plays with individual health-seeking behaviors, stigma is perceived to increase diagnostic delay and subsequent treatment and management of disease (Courtwright and Turner, 2010; Dean and Fenton, 2010).

Societal Impact of STDs in California

The presence of STDs in the United States creates a societal impact. In dollar terms, the societal impact can be indirect (lost wages, etc.), as well as direct (medical care, etc.). Chesson et al. (2008) calculated the direct and indirect cost of STDs in 2006. Translated into 2020 dollars, they estimated that syphilis would cost $734 per case in direct costs and $144 in indirect costs which would translate into a total of $21 million in California in 2018. Congenital syphilis was estimated to cost $8,646 in direct costs and $77,536 in indirect costs per case for a total of $28 million for the 329 cases in 2018. Chlamydia is estimated to cost $89 million in both direct and indirect costs and gonorrhea is estimated to cost $24 million overall in California in 2018. Due to the chronic nature of HIV infection, it is estimated to cost $250,000 in in direct medical costs and $1 million in indirect costs for a total cost of $178 billion in direct and indirect costs.[24] Although the majority of HPV infections resolve on their own, those that don't result in more than 4,600 cervical cancer cases in California each year. Adjusting estimates from Max et al. (2003) for the impact of cervical cancer in California in 1998 to 2020 dollars results in an estimated $327 million in direct and indirect costs related to cervical cancer. Please note: the societal impact discussed here is relevant to a broader population than AB 2204 impacts, which would affect the health insurance of a subset of Californians (see Policy Context). See the *Benefit Coverage, Utilization, and Cost Impacts* section for estimates of cost impacts for the specific population targeted by AB 2204.

[24] Data for the indirect and direct costs per case for each disease was taken from Chesson et al. (2008) and adjusted to 2020 dollars. This figure was then applied to the number of cases presented in Table 1 and added together to get a total combined direct and indirect costs per disease.

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, AB 2204 would alter requirements related to coverage of identified tests and treatments for sexually transmitted diseases (STDs) when provided by "noncontracting health facilities". AB 2204 would define the list of STDs and the relevant tests and treatments through reference to guidelines published by the Centers for Disease Control and Prevention (CDC).

Additional information on STDs, including prevalence figures, is included in the *Background* section. As noted in the *Background* section, this analysis focuses on the 11 most common STDs listed in the 2015 CDC STD Treatment Guidelines (CDC, 2015). Those STDs and their recommended tests and treatments are listed in Table 5, at the end of this section. The medical effectiveness review summarizes findings from evidence[25] on the test and treatments listed in the CDC Guidelines for these STDs.

Research Approach and Methods

CHBRP medical effectiveness analyses typically rely on a thorough and systematic review of the literature in order to identify studies that can help quantify the evidence as pertains to the bill. The ultimate goal of the process is a review of the available studies in order to provide a rating of the effectiveness of the treatments or processes in question. For many of our research questions to be addressed in this specific analysis, we benefit from pre-existing work done by and on behalf of the CDC in their 2015 STD Treatment Guidelines. These guidelines were developed by workgroups of subject matter experts in cooperation with CDC staff. The workgroups comprised multidisciplinary experts from federal, state, and local providers, as well as clinicians and researchers. Much like the standard CHBRP review and analysis process, the workgroups combined the results of systematic reviews of testing and treatments for each STD, with expert experience, opinion, and consensus. As such, the treatments and tests recommended in the treatment guidelines are deemed to be the current gold standard with regard to testing and treatment of STD's, and further review of the literature was not required.

Methodological Considerations

As mentioned above, this analysis relied on the CDC STD Treatment Guidelines (2015), which provide an extensively researched compendium of tests and treatments that are considered standard of care as defined by systematic reviews of the research, expert panels, and clinicians. These guidelines were recently reviewed and updated where necessary by the CDC (CDC, 2020). The review resulted in no changes to the test and treatments recommended in 2015, and as such, the 2015 recommendations remain the standard of care with regard to the testing and treatment of STDs. Our summary of the recommended tests and treatments in the sections to follow are based on this expert consensus by the CDC that tests and treatments recommended in the guidelines are effective.

Sexually Transmitted Diseases

Sexually transmitted diseases (STDs) are defined as a type of disease or infection caused by a pathogen (e.g., bacterium, virus, or other microorganism) that can be transmitted or acquired via direct sexual contact from person to person (CDC, 2015). Obtaining testing and treatment for STDs in a timely manner are key to limiting adverse health outcomes and to reducing the transmission of disease to noninfected partners. Consistent with CDC Guidelines (2015) for general populations, all health care providers

[25] Much of the discussion in this section is focused on reviews of available literature. However, as noted in the section on Implementing the Hierarchy of Evidence on page 11 of the Medical Effectiveness Analysis and Research Approach document (posted at http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php), in the absence of fully applicable to the analysis peer-reviewed literature on well-designed randomized controlled trials (RCTs), CHBRP's hierarchy of evidence allows for the inclusion of other evidence.

and/or OB/GYNs should ask their pregnant patients and their sex partners about STDs; provide counseling regarding potential for perinatal infections; and identify and/or treat pregnant patients diagnosed with STDs during their initial and/or subsequent prenatal visits.

Categories and Types of STDs

STDs can be categorized into four classes of diseases (below and Table 2). These classifications are largely based on the source cause of the conditions they contain (e.g., bacterial versus viral), and thus there is a general commonality of treatments types within each category. Additionally, and due to the same reasons, there is a clustering of treatment prognoses within each category, with bacterial, ectoparasitic, and protozoal having treatments that are often curative, whereas treatments for conditions in the viral category often being more for the management of symptoms.

1) Bacterial: Within the bacterial class, common STDs include: (1) bacterial vaginosis; (2) chlamydial infections (i.e., chlamydia); (3) gonococcal infections (i.e., gonorrhea); and (4) syphilis.
2) Viral: Within the viral class, common STDs include: (1) genital herpes simplex (i.e., herpes); (2) hepatitis B; (3) HIV; and (4) human papillomavirus.
3) Ectoparasitic: Within the ectoparasitic class, common STDs include (1) pediculosis pubis (i.e., pubic lice) and (2) scabies.
4) Protozoal: Among the protozoal class, common STDs include trichomoniasis.

Study Findings

This following section summarizes CHBRP's findings regarding the strength of evidence for the effectiveness of the tests and treatments that are the standard of care for STDs as recommended by the 2015 CDC STD Treatment Guidelines. As mentioned above, these guidelines are considered to be the standard of care for the treatment of STDs, and as such, an assumption of a clear and convincing level of demonstrated effectiveness is an underlying constant of this summary and analysis.

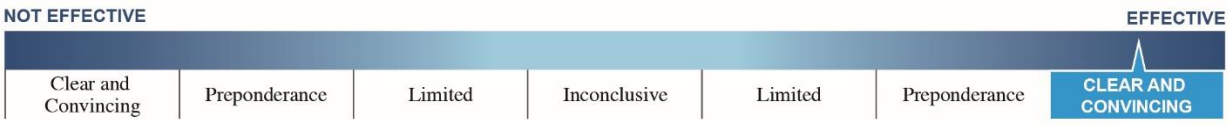
The CDC STD Treatment Guidelines (2015) are consider the undisputed standard of care for the testing and treatment of STDs. CHBRP found clear and convincing evidence based on these guidelines that:

1) The recommended tests and treatments effectively cure or manage the listed STDs.

2) Untreated, the listed STDs can lead to serious health complications.

3) Treatment of the listed STDs reduces transmission.

Figure 1. Medical Effectiveness of STD Tests and Treatments Recommended by the CDC



The 11 STDs included in this analysis are presented in order based on category as described above. In addition to the summary of each STD provided, additional details regarding testing and treatments are presented in Table 5.

Bacterial

Bacterial Vaginosis

Description: Bacterial vaginosis (BV) is a polymicrobial infection that can occur within the vagina with high concentrations of a certain type of anaerobic bacteria (e.g., *Prevotella* sp. and *Mobiluncus* sp.) (CDC, 2015). This results in an imbalance of normal bacteria in the vagina. Despite researchers not having a clear understanding regarding the cause of BV, the CDC (2015) reports that BV typically occurs in sexually active women, and rarely affects women who have not engaged in sexual activity. Other factors related to increased risk for BV include: having a new sex partner or multiple sex partners; opting out of using a protective barrier during sex (e.g., condom, dental dam); and douching, which can alter the balance of bacteria in the vagina (CDC, 2015). Although some women with BV may present as asymptomatic, others may experience symptoms such as: a thin white or gray vaginal discharge; pain or burning sensation within the vagina; a malodor, especially post-sexual activity; a burning sensation while urinating; and/or interior/exterior itching of the vagina (CDC, 2015).

Testing and Treatment: BV is most commonly detected through the use of Gram stain, which is considered the gold standard with regard to diagnostic methods for this condition. Primary recommended treatments are metronidazole (oral or topical gel) or clindamycin (topical cream).

If Left Untreated: Although the main benefit to the above described treatments is a reduction in symptoms and control of infection, treatments benefits also include reduced risk for acquiring multiple secondary conditions, including HIV (CDC, 2015). Despite BV having the potential to go away untreated; if left untreated, BV can lead to serious health outcomes, including increased risk for acquiring other STDs or HIV if engaging in sex with someone who is infected with HIV; increased risk for transmitting HIV to partner if HIV positive; increased risk for complications related to pregnancy such as preterm delivery; and increased risk for reacquiring BV (CDC, 2015).

Chlamydial Infection (i.e., Chlamydia)

Description: Chlamydia is one of the most commonly reported bacterial STDs. It is caused by *Chlamydia trachomatis* that can occur in both women and men (CDC, 2015). Chlamydia is spread through participating in sexual activity (i.e., vaginal, anal, or oral) with a partner who has chlamydia (CDC, 2015). A majority of individuals who have chlamydia do not present with any symptoms; however, if symptoms do appear, they may not present until several weeks after sex with an infected partner (CDC, 2015). Women presenting with chlamydia may experience an abnormal vaginal discharge and/or a burning sensation while urinating. Men presenting with chlamydia may experience a discharge from their penis; a burning sensation while urinating; and/or, while less common, pain or swelling in the testes (CDC, 2015). Men or women may also experience symptoms in their rectum — if they engaged in anal sex — such as rectal pain, discharge, and/or bleeding.

Testing and Treatment: Nucleic acid amplification (NAAT) testing is the most sensitive detection method for chlamydial infection. For both men and women, NAAT testing involves the collection of urine or obtaining a specimen from the vagina or endocervix, which is then subjected to NAAT testing. Recommended treatments take the form of antibiotics such as azithromycin (oral, single dose) or doxycycline (oral, twice daily for 7 days). The CDC STD Treatment Guidelines report cure rates of between 97% and 98% for these treatments (CDC, 2015).

If Left Untreated: If left untreated, chlamydia can lead to serious health outcomes. Among women, untreated chlamydia can lead to pelvic inflammatory disease (PID), leading to permanent damage of the reproductive system; long-term pelvic pain; infertility; and/or ectopic pregnancy (i.e., pregnancy outside the uterus) (CDC, 2015). Although men rarely experience long-term health problems, infection can spread to the tube carrying sperm from the testicles (i.e., epididymis), leading to pain and fever (CDC, 2015).

Gonococcal Infections (i.e., Gonorrhea)

Description: Gonorrhea is a bacterial STD caused by *N. gonorrhoeae* infections (CDC, 2015). Gonorrhea can be acquired through sexual contact with the penis, vagina, mouth, or anus of an infected partner (CDC, 2015). Gonorrhea can also be transmitted from mother to baby (i.e., perinatally) during childbirth (CDC, 2015). Many men infected with gonorrhea present as asymptomatic; however, for those presenting with signs and symptoms, they can experience dysuria (i.e., pain in urinating) or a white, yellow, or green urethral discharge that will typically appear between 1 and 14 days after infection (CDC, 2015). Individuals may also experience testicular or scrotal pain, in which epididymitis is found to co-occur with a urethral infection (CDC, 2015). Similarly, most women infected with gonorrhea are also asymptomatic (CDC, 2015). According to the CDC (2015), when a woman experiences mild or nonspecific symptoms, providers can often mistake them for a bladder or vaginal infection. Other symptoms can include: dysuria, increased vaginal discharge, and/or vaginal bleeding (not associated with a period) (CDC, 2015).

Testing and Treatment: Both culture and nucleic acid amplification (NAAT) testing can be used to detect infection with gonorrhea. NAAT is the most sensitive detection method. Culture testing involves obtaining endocervical swab samples for women or urethral swab samples for men. For both men and women, NAAT testing can utilize multiple types of specimens including urine, endocervix or urethral swabs. The recommended treatment for gonorrheal infections takes the form of a dual therapy using two antimicrobials. Most commonly, cetriaxone (IM injection, single dose) and azithromycin (oral, single dose), are administered together (preferably simultaneously or as close together as possible). This dual therapy treatment has a 98% to 99% cure rate and has been deemed safe (CDC, 2015).

If Left Untreated: If left untreated, gonorrhea can cause serious and permanent health outcomes in both men and women (CDC, 2015). Among women, gonorrhea can lead to pelvic inflammatory disease (PID), in which symptoms can range from mild to severe, and can include abdominal pain and fever (CDC, 2015). PID can subsequently lead to internal abscesses; chronic pelvic pain; infertility; and/or ectopic pregnancy (CDC, 2015). Among men, gonorrhea can lead to epididymitis, and in rare cases, to infertility (CDC, 2015). Among men and women, gonorrhea can also spread to the blood, leading to a potentially life-threatening disseminated gonococcal infection (DGI), which can be characterized as arthritis; tenosynovitis; and/or dermatitis (CDC, 2015).

Syphilis

Description: Syphilis is a bacterial STD that can be divided into four stages, including primary, secondary, latent, tertiary (CDC, 2015). In 2018, California reported more than 25,000 cases of syphilis (inclusive of all stages), a 265% increase over 10 years ago (CDPH, 2018c). According to the California Department of Health (2018c), syphilis has grown into a major public health issue, with rates increasing in all regions of the state, among all sexes. Furthermore, the number of infants born to infected Californian mothers increased for the 6th year in row, equal to 329 cases of congenital syphilis in 2018 (CDPH, 2018c). Syphilis can be acquired or transmitted via sexual contact (i.e., vaginal, anal, or oral) and/or perinatally (i.e., from an infected mother to baby) (CDC, 2015).

Symptoms and signs vary by stage of the disease. Common signs and symptoms of primary syphilis include ulcers or chancre (i.e., painless ulcers) at the site of infection that may last 3 to 6 weeks, whereas secondary syphilis symptoms may include: skin rash; mucous membrane lesions; fever; and/or lymphadenopathy (i.e., swollen lymph glands), to name a few (CDC, 2015). Latent syphilis is the stage in which persons present as asymptomatic—a person can continue to live with latent syphilis for many years without detection of any signs or symptoms (CDC, 2015). Although a majority of persons with untreated syphilis do not develop tertiary syphilis, tertiary syphilis can affect many different organ systems, in which symptoms would occur 10 to 30 years post-initial infection (CDC, 2015).

Testing and Treatment: Testing for syphilis is by means of darkfield examinations accompanied by tests to detect the bacterium *Treponema pallidum.* Darkfield microscopy is a method for rendering unstained and transparent specimens to be visible. If the initial examinations for syphilis indicate probable infection,

confirmation requires two paired tests, one being treponemal (looks for the antibody to *T. pallidum*) with the other nontreponemal (looks for damaged cells). For all stages, the recommended treatment for syphilis is penicillin G. Form, dosage, and administration methods vary by stage. Late and tertiary syphilis require longer-term therapy.

If Left Untreated: If left untreated, syphilis can result in severe health outcomes. For example, early neurologic clinical manifestations can result in cranial nerve dysfunction; meningitis; stroke; acute altered mental state; auditory or ophthalmic abnormalities; and/or death if left untreated through the tertiary stage (CDC, 2015). Moreover, congenital syphilis can result in miscarriage; stillbirth; premature birth or low birth weight; and/or infant death shortly after birth (CDC, 2015).

Viral

Genital Herpes Simplex (i.e., Genital Herpes)

Description: Genital herpes is an STD caused by two types of viral infections, including HSV-1 and HSV-2 (CDC, 2015). It is spread through having sex (i.e., vaginal, anal, or oral) with someone who has the disease (CDC, 2015). Furthermore, herpes can be acquired through contact with a herpes sore; saliva or genital secretions; and/or skin in the oral/genital area if a partner has an oral/genital herpes infection, respectively (CDC, 2015). According to the CDC (2015), a majority of individuals who have genital herpes do not present with symptoms or may experience very mild symptoms; in fact, individuals with herpes may mistake them for another skin condition such as a pimple or ingrown hair. Individuals presenting with genital herpes may have one or more blisters on or around the genitals, rectum, or mouth (also referred to as herpes sores) (CDC, 2015). Located within/near the skin/lining of the mouth, vagina, or rectum, herpes blisters can break into painful sores that can last for 1 or more weeks (CDC, 2015). Herpes sores can also be referred to as an “outbreak,” which can also lead to flu-like symptoms, including fever, body aches, and/or swollen glands (CDC, 2015). Individuals who experience an outbreak are also prone to experiencing subsequent outbreaks, especially if the infection is due to HSV-2 (CDC, 2015).

Testing and Treatment: Virologic and serologic tests are the recommended diagnostic tools for HSV. These tests are required to be type-specific (HSV-1 versus HSV-2), and are available in most clinical settings that treat STDs. Virologic tests take the form of cell culture or polymerase chain reaction (PCR) testing. Serologic tests are point-of-care tests requiring a blood sample. As HSV is a viral infection, condition management versus cure is the goal of treatment. Treatments differ depending on the episodic stage of the condition. First episodes (initial treatment) of HSV are treated with antiviral therapy in the form of acyclovir (oral, three times daily for 7 days), valacyclovir (oral, twice daily for 7 days), or famciclovir (oral, three times per day for 7 days). Treatment for established infections and recurrent episodes have the goal of shortening the duration and intensity of symptoms during the outbreak and utilize differing dosages and durations of the antiviral medications mentioned above (CDC, 2015).

If Left Untreated: If left untreated, genital herpes can lead to painful genital sores, which can also be intensified in people with suppressed immune systems (CDC, 2015). Furthermore, if an individual unknowingly touches a sore/fluid from the sore, the individual may unintentionally transfer herpes from one section of the body to another (CDC, 2015).

Hepatitis B

Description: Hepatitis B (HBV) is an acute or chronic infection caused by the hepatitis B virus (CDC, 2015). HBV can be acquired through percutaneous contact (i.e., puncture of the skin) as well as mucosal contact with infectious blood or bodily fluids, such as having vaginal, anal, or oral sex with an infected partner (CDC, 2015). Risk for chronic infection is inversely associated with age of acquisition; approximately 90% and 30% of infected infants and children less than 5 years of age, respectively, become chronically infected compared to 2% to 6% of those infected as adults (CDC, 2015). Newly acquired HBV can present as asymptomatic or symptomatic. If symptoms do occur, they can begin within

a range of 60 to 150 days post-exposure to HBV and can include: fever; fatigue; loss of appetite; nausea; vomiting; abdominal pain; dark urine; jaundice; clay-colored bowel movements; and/or joint pain (CDC, 2015).

Testing and Treatment: Diagnosis of hepatitis B infection requires a blood (serum) sample, which is evaluated for the hepatitis B surface antigen, hepatitis B surface antibody, and hepatitis B core antibody. There are no specific treatments available for hepatitis B that will result in alleviation of the condition. FDA-approved antiviral medications such as entecavir, tenofir, and lamivudine are available that can suppress replication as well as moderate associated liver disease (CDC, 2015).

If Left Untreated: If left untreated, some acute HBV infections will resolve on their own, whereas others can develop chronic infection leading to cirrhosis or hepatocellular carcinoma (i.e., liver cancer) (CDC, 2015). Moreover, approximately 1% of reported cases can lead to liver failure or death according to the CDC (2015).

Human Immunodeficiency Virus

Description: Human immunodeficiency virus (HIV) is defined as a brief acute retroviral syndrome that weakens a person's immune system by progressively depleting important cells that fight disease and infection (i.e., CD4 T-lymphocyte cells) (CDC, 2015). HIV can be acquired or transmitted through mucosal contact with bodily fluids (such as having anal or vaginal sex) of an infected partner; breast milk; or via needle/syringe use. In the United States, HIV is predominantly spread through unprotected anal or vaginal sex with an infected partner and through the sharing of needles, syringes, or rinse water used to prepare drugs for injection with someone who has HIV (CDC, 2015). In rare cases, HIV has spread via oral sex with an infected person or through blood transfusions (CDC, 2015). Persons infected with other STDs such as early syphilis, gonorrhea, or chlamydia are considered at high risk for acquiring HIV (CDC, 2015). Individuals who have newly acquired HIV may experience flu-like symptoms (e.g., fever, chills, rash, night sweats, muscle aches, sore throat, fatigue, swollen lymph nodes, or mouth ulcers) within 2 to 4 weeks after infection (also referred to as Stage 1 HIV infection) (CDC, 2015), in which symptoms can last anywhere between several days and a few weeks (CDC, 2015).

Testing and Treatment: Detection of HIV infection is often accomplished through screening of individuals who undergo treatment for STDs. Although the CDC recommends screening for individuals in these circumstances, the patient can decline or defer screening. Diagnostic tests take the form of analysis of blood (serum) that identify the antigen and antibodies produced in response to infection. Rapid HIV tests are available that can provide results in clinical settings within 30 minutes. As with other viral infections, treatment for HIV infection most often takes the form of multidimensional support and treatment regimes. After initial diagnosis, persons are provided information regarding the importance of prompt and continuous medical care, treatment options, and next steps in care. Initial care often includes counseling because the psychological impact of a diagnosis of HIV can be severe. This can also include referrals to specialty care, behavioral interventions, reproductive choices and contraception, and risk-reduction strategies. HIV medications (antivirals) reduce likelihood of infecting others as well as enhancing immune function and suppressing replication (CDC, 2015)

If Left Untreated: If left untreated, HIV will typically progress through three stages (CDC, 2015). Stage 1, also referred to as acute HIV infection, typically presents as flu-like symptoms, lasting anywhere from several days to a few weeks (CDC, 2015). Individuals with acute HIV infection are highly contagious during this period as large amounts of virus are present within the blood (CDC, 2015). Individuals in Stage 2, also referred to as clinical latency (HIV inactivity or dormancy), typically are asymptomatic (CDC, 2015). During this time, HIV reproduces at lower levels compared to Stage 1 (CDC, 2015). For those not seeking treatment, individuals can remain in Stage 2 for a decade or longer, whereas others may progress through Stage 2 at a faster rate (CDC, 2015). Stage 3, also referred to as acquired immunodeficiency syndrome (AIDS), is the most severe stage of HIV infection. If left untreated, individuals with AIDS can have severe health outcomes, including damaged immune systems that can

lead to a number of severe illnesses (i.e., opportunistic illnesses) (CDC, 2015). The survival rate for individuals with untreated AIDS is typically around 3 years (CDC, 2015).

Human Papillomavirus

Description: According to the CDC (2015), approximately 100 types of human papillomavirus (HPV) infections have been identified, of which at least 40 are known to infect the genital area. According to the CDC (2015), a majority of HPV infections are self-limited and present as asymptomatic. If left untreated, HPV can increase the risk for several types of cancer. For example, oncogenic (i.e., leading to the development of a tumor or tumors) high-risk HPV infection (e.g., HPV types 16 and 18) can lead to a number of cancers and precancers such as cervical, penile, vulvar, vaginal, anal, and oropharyngeal (CDC, 2015). According to the California Cancer Facts and Figures (2017), more than 99% of cervical cancers are related to HPV. However, the prevalence of oncogenic HPV is decreasing due to the development of an effective vaccine. Alternatively, nononcogenic, low-risk HPV infection (e.g., HPV types 6 and 11) can lead to the development of genital warts and/or recurrent respiratory papillomatosis (CDC, 2015).

Testing and Treatment: Testing for the HPV virus is limited to oncogenic types and usually occur during screening for cervical cancer. Treatment is generally targeted to the symptoms or physical manifestations that occur due to infection with the virus. These include anogenital warts or precancerous lesions. Diagnosis for anogenital warts is generally through visual inspection and confirmation through biopsy of tissue samples. As genital HPV infection usually clears with no treatment, antiviral therapy is not recommended. It is important to note that treatment of anogenital warts caused by HPV can take many forms, and the CDC treatment guidelines do not recommend any one specific regimen as each case requires customization and adjustment for greatest effect. Most clinicians employ a combination therapy involving usually comprising cryotherapy administered by the provider along with patient applied topics creams or ointments (CDC, 2015).

If Left Untreated: If left untreated, HPV can increase the risk for several types of cancer, including cervical and anal cancers. According to the American Cancer Society et al. (ACS et al., 2017), more than 99% of cervical cancers are related to HPV.

Ectoparasitic

Pediculosis Pubis (i.e., Pubic Lice)

Description: Pubic lice are classified as an ectoparasitic STD in which parasitic insects are found in the pubic or genital area of an infected person (CDC, 2015). Pubic lice can be acquired or transmitted through sexual contact and/or contact with clothing/bedding shared with an infected person (CDPH, 2017). Pubic lice can present in three forms, including nit form (i.e., lice eggs), nymph form (i.e., an immature louse that has recently hatched from an egg), and adult form (i.e., fully grown insect resembling a miniature crab about the size of a sesame seed (2–4 mm long)) (CDC, 2015). Signs and symptoms of infected persons include: itching within or around the genital area; development of a rash around the genital area; and visible nits or crawling lice within the genital area (CDC, 2015).

Testing and Treatment: Testing for pubic lice is through visual examination. Recommended treatment is permethrin cream rinse or pyrethrins with piperonyl butoxide (both topical applications rinsed after 10 minutes) (CDC, 2015).

If Left Untreated: If left untreated, long-term public lice can lead to discoloration of skin, especially around the waist, groin, or upper thighs (also known as Vagabond's disease) (CDPH, 2017a). Due to the intensity of itchiness, pubic lice may also lead to secondary bacterial or fungal infections as a result of frequent scratching (CDPH, 2017a).

Scabies

Description: Scabies are classified as an ectoparasitic STD in which human itch mites burrow into the upper layer of skin within infected persons (CDC, 2015). Scabies can be transmitted through household members and/or sexual activity with an infected partner. Among adults, scabies is frequently transmitted via sexual activity (CDC, 2015). Common symptoms include itching; development of a skin rash (i.e., a pimple-like rash also referred to as "scabies rash"); and severe itching (i.e., pruritus) that often takes place during nighttime (CDC, 2015). Itching and development of a rash can spread throughout the body or can be limited to certain areas of the body such as between the fingers, wrist, elbow, armpit, penis, nipple, waist, and/or buttocks (CDC, 2015).

Testing and Treatment: Diagnosis for scabies is generally through visual inspection often followed by microscopic examination of scraping samples. Recommended treatment is Permethrin cream applied to the entire body and rinsed after 8 to 14 hours, or ivermectin (oral, 2 doses 2 weeks apart) (CDC, 2015).

If Left Untreated: If left untreated, intense itching can lead to frequent scratching that can lead to skin sores (CDC, 2015). Skin sores can lead to secondary infections of the skins such as *Staphylococcus aureus* or beta-hemolytic streptococci (CDC, 2015). If bacterial infections are left untreated, prolonged infections can lead to inflammation of the kidneys (also referred to as post-streptococcal glomerulonephritis) (CDC, 2015).

Protozoal

Trichomoniasis (i.e., Trich)

Description: Trich is caused by a protozoal parasitic infection (CDC, 2015). Trich is spread through sexual activity with an infected person; for example, from a penis to a vagina, from a vagina to a penis, or from a vagina to another vagina (CDC, 2015). Among women, trich commonly infects the lower genital tract such as the vulva; vagina; or cervix; and among men, trich commonly infects the inside of the penis (also known as the urethra) (CDC, 2015). Trich typically does not infect other body parts not formerly listed such as the hands, mouth, or anus (CDC, 2015). Among those infected, approximately 70% do not present with any signs or symptoms (CDC, 2015). However, for those who do experience symptoms, symptoms can include mild irritation to severe inflammation, with some presenting with symptoms within as early as 5 to 28 days after initial exposure (CDC, 2015). Symptoms have also been reported to come and go, with men experiencing an itching or irritation within the penis; burning after urination or ejaculation; and/or discharge from the penis (CDC, 2015). Similarly, women may experience an itching, burning, or redness of the genitals; discomfort while urinating; and/or an anomaly in their vaginal discharge (such as a thinner discharge or increased volume of discharge) (CDC, 2015).

Testing and Treatment: The most common form of testing for trich is wet-mount preparations of genital secretions that are then analyzed under a microscope. However, this method has low sensitivity and is only in use due to its low cost and also its ability to perform rapidly in-house. Increasingly popular are tests with higher sensitivity such as nucleic acid amplification testing (NAAT) or the OSOM Trichomonas Rapid Test. These types of tests are both highly specific and sensitive, and are recommended when available. The most common treatments for trich take the form of antimicrobial medications such as metronidazole (oral, single dose) or tinidazole (oral, single dose). These medications are known to be effective against trich infections and have cure rates of 92% to 100% (CDC, 2015).

If Left Untreated: If left untreated, trich can persist for several months up to a number of years (CDC, 2015). Furthermore, untreated trich can increase the risk for acquiring or transmitting other STDs. For example, trich can lead to genital inflammation, which can subsequently increase the likelihood for acquiring HIV or passing HIV to an uninfected partner via sexual activity (CDC, 2015).

Table 3. STD Tests and Treatments

STD	Brand-Name (Only) Drug	Generic Drug	Other Treatment	USPSTF General Population (a)	USPSTF Increased Risk (a)	Test (b)	Detection Method (b)
Bacterial STDs							
Bacterial vaginosis		• Metronidazole (oral/cream) • Clindamycin (cream)	N/A			Vaginal swab; urine sample	Gram Stain
Chlamydial infections		• Azithromycin • Doxycycline • Erythromycin base Ethylsuccinate	N/A	**B** Sexually active women age ≤24	**B** Women age >24 at increased risk	Vaginal swab; Urine sample	NAAT
Gonococcal infections		• Ceftriaxone • Azithromycin	N/A	**B** Sexually active women ≤24	**B** Women age >24 at increased risk	Vaginal swab; urine sample	NAAT
Syphilis	• Bicillin L-A • Pfizerpen • Bicillin C-R	• Benzathine penicillin G • Aqueous crystalline penicillin G • Procaine penicillin G	N/A		**A** All pregnant women, Men and women at increased risk	Blood sample	Darkfield; DFA-TP; PCR
Viral STDs							
Genital herpes simplex	• Valtrex • Famvir	• Acyclovir • Valacyclovir • Famciclovir	N/A			Blood sample; viral culture	Cell culture; DFA; PCR
Hepatitis B		None	Refer to a provider for management		**A** All pregnant women; men and women at increased risk	Blood sample	HBsAg (Hep B surface antigen)
HIV		None	Refer to a provider for management	**A** Ages 15 to 65	**A** <15 or >65 at increased risk; all pregnant women; men and women at increased risk	Blood sample; oral sample	HIV antibody and p24 antigen

Human papillomavirus	• Condylox • Veregen	• Imiquimod • Podofilox (solution or gel) • Sinecatechins	Cryotherapy; trichloroacetic OR bichloroacetic acid; surgical removal	**A** Pap every 3 yrs (women age 21–65) OR Pap + HPV test every 5 yrs (women age 30–65)	Cervical swab	Hybrid capture 2; PCR
Ectoparasitic STDs						
Pediculosis pubis		• Permethrin (cream rinse) • Pyrethrins with piperonyl butoxide	N/A		Visual exam	N/A
Scabies	• Stromectol	• Permethrin (cream) • Ivermectin	N/A		Visual exam; scraping sample	Microscopic examination
Protozoal STDs						
Trichomoniasis		• Metronidazole • Tinidazole	N/A		Urine sample; vaginal/ urethral swab	NAAT; wet prep; culture

Source: CHBRP, 2020 – adapted from the CDC (2015).

Notes: (a) Grades A and B (in bold) from the USPSTF are relevant to the ACA's federally selected preventive services mandate, which can prohibit cost sharing.

(b) Data from Lee et al. (2016).

Key: ACA = Affordable Care Act; DF= direct fluorescent antibody; NAAT = nucleic acid amplification test; PCR = polymerase chain reaction; TP = *Treponema pallidum*; USPSTF = United States Preventative Services Task Force.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, AB 2204 would identify a set of tests and treatments related to the most common sexually transmitted diseases (STDs) referred to in the 2015 *CDC STDs Treatment Guidelines*, the most current version available (CDC, 2015). AB 2204 references licensed noncontracting (with the particular health plan or insurer) health facilities that are contractors with the state or county to provide clinical STD services. In this analysis, these will be referred to as "clinics." AB 2204 would require DMHC-regulated health plans and CDI-regulated policies to reimburse such clinics (when the clinic is out-of-network for that particular plan or policy) as in-network providers. For those services, AB 2204 would require that enrollees pay only in-network cost sharing.

This section reports the potential incremental impacts of AB 2204 on estimated baseline benefit coverage, utilization, and overall cost. Currently, 61.5% of enrollees in DMHC-regulated plans and CDI-regulated policies have health insurance that would be subject to AB 2204. Benefit coverage of enrollees in Medi-Cal managed care plans would not be subject to AB 2204, as explained in the *Policy Context* section.

In this analysis, CHBRP estimates the benefit coverage, utilization, and costs for test and treatments related to the most common STDs identified in the 2015 CDC STDs Treatment Guidelines. For a complete list of all tests and treatments included, see the Medical Effectiveness section. HIV medications (antiretrovirals) are discussed in the 2015 CDC Guidelines, although not in the same manner as the other tests and treatments. HIV medications are included in this analysis, but as they have a very different utilization pattern (chronic, lifetime use being the norm, rather than the more common use of a single-filled prescription) and as they have a much higher unit cost, they are presented separately from the other STD services in Table 1. Some other treatments, including medications for genital warts and herpes, also include multiple prescriptions over the course of 1 year, but as the cost and utilization are similar to other STD treatments, they are included in the aggregate.

CHBRP has made a number of analytic assumptions, including:

- AB 2204 would not impact coverage for preventive services.
- Tests for the most common STDs are based on having symptoms that would indicate that testing is medically appropriate, which would limit the potential increase in utilization.
- Out-of-network STD clinics would be able to absorb a projected increase in utilization postmandate, as there is no shortage in the workforce required to perform STD testing (nonclinicians are frequently utilized) and no current delays in providing services.

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

Baseline and Postmandate Benefit Coverage

Current coverage of tests and treatments for the most common STDs at out-of-network clinics was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represent 51% of enrollees with private market health insurance that can be subject to state mandates. Because the mandate in AB 2204 pertains to in-network versus out-of-network benefit coverage, the carrier responses alone were insufficient to create a CHBRP Cost Model that adequately reflected the insured population of enrollees subject to the mandate.[26] The benefit coverage,

[26] Closed network HMOs generally offer coverage for all services only if an enrollee is in emergency situation, including travelling to an area in which the HMO has no in-network providers. An STD clinic may therefore be

utilization, and cost estimates in this section are therefore reflective of the modeled enrollee population, reflecting the known commercial/CalPERS ratio of PPO versus HMO enrollment. See Appendix C for a full explanation of the model.

Currently, among commercial/CalPERS enrollees (see Table 1):

- 0% have coverage that would reimburse out-of-network clinics providing STD tests and treatments at in-network rates and have in-network cost sharing for out-of-network clinics.
- However, 28% of enrollees have benefit coverage that includes reimbursement and copays at out-of-network clinics at currently established out-of-network rates.
- The remaining 72% of enrollees have benefit coverage that does not include payments for any out-of-network STD clinic tests or treatments, excepting those done under emergency circumstances or when the enrollee is out-of-area for all in-network providers.

Postmandate, 100% of commercial/CalPERS enrollees would have benefit coverage, which includes cost sharing and reimbursement at in-network rates for tests and treatments of the most common STDs provided by some out-of-network clinics (those receiving state/county STD funds).

Almost all — over 94% — commercial/CalPERS enrollees have a pharmacy benefit regulated by DMHC or CDI that covers both generic and brand name outpatient prescription medications.[27] Though such enrollees would still have no pharmacy benefit when receiving care form an in-network provider, they would gain benefit coverage from AB 2204 for outpatient medications for STDs when accessed through some out-of-network clinics. Although CHBRP cannot estimate the figure, there would be some additional administrative costs for those plans and policies (to create outpatient medication coverage applicable only when accessed through some out-of-network clinics).

Baseline and Postmandate Utilization

Utilization estimates were derived from the Milliman claims dataset. CHBRP assumes AB 2204 will lead to an overall increase of STD services driven by reducing cost sharing for enrollees as well as increasing funding for such services at noncontracted publicly funded healthcare facilities. Additionally, because STD services will have lower cost sharing at a broader range of locations, it will be more convenient for many enrollees to receive such services.

The mandate will cause utilization shifts between out-of-network, in-network, and self-pay services, as enrollees respond to having more options with low cost sharing. CHBRP assumes that some, but not all, self-pay services with unreported insurance coverage will now become out-of-network services. For a complete review of the assumed utilization shifts, which were created with input from the content expert,[28] see Appendix C.

As discussed in the “How Lack of Benefit Coverage Shifts Costs to Other Payers” section below, enrollees who self-pay have their costs reduced through other funding sources beyond insurance coverage, and also have privacy concerns that often determine whether they will report having insurance, CHBRP assumes that some in-network services will shift to out-of-network services due to the convenience and reimbursement parity. Projected out-of-network cost sharing is based on the postmandate proportion of services subject to reimbursement parity. For a complete review of how utilization was determined, see Appendix C.

included under this type of coverage, even though it would not be considered to be in-network and there is no established out-of-network coverage option.

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

[28] Personal communication with Dr. Tri Do, UCSF, on March 10, 2020.

Currently, CHBRP estimates that 24,951 commercial/CalPERS enrollees use HIV medications received from an in-network provider (Table 1) and that, given the high unit costs for HIV medications and the higher cost sharing that can be applicable, no measurable number of enrollees use out-of-network providers. Postmandate, there would be a shift to some use of out-of-network STD clinics, with an estimated 749 enrollees using HIV medications from these providers. Among enrollees using HIV medications, CHBRP estimates no measurable number of enrollees who self-pay (again, due to the high unit costs), either at baseline or postmandate.

For all other tests and treatments related to common STDs (including office visits, diagnostic tests, antibiotic prescriptions, and minor surgeries), CHBRP estimates that currently 1,286,605 commercial/CalPERs enrollees use in-network providers, 80,164 enrollees use out-of-network clinics covered by insurance, and 428,868 enrollees self-pay (Table 1). Commercial/CalPERS enrollees (and others) commonly choose to conceal their insurance status and self-pay for STD tests and treatments due to privacy concerns, particularly in relation to other family members that may share their same insurance plan. Such privacy concerns are especially common among adolescents and young adults using their parents' insurance (Pearson, et al, 2016).

In Table 3, CHBRP presents the different STD tests and their respective utilization among the total commercial/CalPERS enrollee population. These range from 20,952 for scabies to 952,378 for chlamydial infections.

Table 4. Baseline STD Test Utilization Among Commercial/CalPERS Enrollees, 2020

	Total Tests for All Enrollees Subject to AB 2204
Bacterial vaginosis	92,533
Chlamydial infections	952,378
Gonococcal infections	896,714
Syphilis	415,286
Genital herpes simplex	193,759
Hepatitis B	682,431
HIV	78,113
Human papilloma virus	748,681
Scabies	20,952
Trichomoniasis	190,577

Source: California Health Benefits Review Program, 2020.

Note: Number of tests may not correspond to the population prevalence reported in the *Background* section, as some STDs are more often diagnosed through a medical examination of symptoms rather than a diagnostic test.

Postmandate, CHBRP estimates that there will be an overall increase in utilization of STD tests and treatments at out-of-network STD clinics, with 86,819 more enrollees using these services (Table 1). CHBRP also estimates a decrease in the use of in-network providers for STD services by 38,581, as people shift to using STD clinics now that the cost sharing would be the same under AB 2204. There will with a smaller decrease of 2,680 enrollees using services at an out-of-network STD clinic through self-pay.

Baseline and Postmandate Per-Unit Cost

CHBRP assumes that in-network and self-pay unit costs do not change postmandate. However, projected out-of-network unit costs are based on the postmandate proportion of out-of-network services subject to reimbursement parity, that is, the proportion of out-of-network services occurring at noncontracted publicly funded health care facilities. To ensure an accurate adjustment, baseline unit costs are adjusted for the "mix" of services.

Currently, HIV medications unit costs average of $1,965 for a 1-month supply, and that is not expected to change under AB 2204.

For other STD tests and treatments, the current average unit cost is $63 for services provided at an in-network facility, $43 at an out-of-network STD clinic, and $61 for self-pay. At baseline, the difference in unit cost between in-network and out-of-network is driven by two factors. First, out-of-network services have a mix of services that included more of the less costly services. For instance, a higher proportion of lab work is performed by out-of-network providers and lab work is typically less costly than office visits. Second, as is common for all services, there is a lower reimbursement rate for out-of-network services compared to in-network services.

Postmandate, a greater proportion of out-of-network services being reimbursed at in-network rates, along with increased use of higher cost services, will raise the average of out-of-network unit cost to $46, but the other two are expected to remain the same.

Baseline and Postmandate Expenditures

AB 2204 would increase total net annual expenditures by $9,668,000, or 0.0074%, for enrollees with commercial/CalPERS DMHC-regulated plans and CDI-regulated policies (Table 1). This is due to a $10,514,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits and enrollee expenses for covered benefits, adjusted by a $846,000 decrease in enrollee expenses for noncovered benefits.

Premiums

CHBRP anticipates that changes in premiums as a result of AB 2204 would vary by market segment, related to the number of enrollees with health insurance that would be subject to AB 2204. However, because of the simulated nature of the Cost Model for AB 2204, CHBRP is unable to differentiate impacts in premiums by market segment beyond what is presented in Table 1.

On average, premium expenditures for private employers for group insurance would increase by 0.0119%. Premium expenditures s among CalPERS HMO employers are estimated to increase by 0.0084% (Table 1).

Enrollee Expenses

AB 2204–related changes in enrollee expenses for covered benefits (deductibles, copays, etc.) and enrollee expenses for noncovered benefits would vary by market segment but CHBRP is unable to quantify those changes. CHBRP projects no change to copayments or coinsurance rates but does project an increase in utilization of STD tests and treatments, including HIV medication treatment, and therefore an increase in total enrollee cost sharing. It is possible that some enrollees incurred expenses related to STD tests and treatments for which coverage was denied, but CHBRP cannot estimate the frequency with which such situations occur and so cannot offer a calculation of impact.

Out-of-pocket spending for covered and noncovered expenses

CHBRP is unable to estimate cost-sharing reductions or increases, as insurance copays are commonly modified by state or county funding at STD clinics. See "How Lack of Benefit Coverage Shifts Costs to Other Payers" below for a full explanation.

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

CHBRP does not project any cost offsets or savings in health care that would result because of the enactment of provisions in AB 2204. With an increase in STD testing, however, it is possible that more appropriate preventive health care will be administered over time, and will lead to better health outcomes. This will be discussed more fully in 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.

CHBRP is aware of the creation of a new pharmacy benefit for the 5% of enrollees in DMHC-regulated plans or CDI-regulated policies specifically for STDs treatments provided at an out-of-network state-funded STD clinic, but is not able to estimate the potential administrative costs for this new benefit.

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), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 2204.

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 2204.

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

Although a significant amount of self-pay currently exists among enrollees in DMHC-regulated plans or CDI-regulated policies, research literature suggests that only some is related to the out-of-pocket cost of STD tests or treatments (Montgomery, et al, 2017; Pearson, et al, 2016; Washburn, et al, 2014). Privacy concerns is a common reason for wanting to pay out-of-pocket even when insurance coverage exists. STD clinics commonly have state or county contracts that reduce out-of-pocket costs for tests and treatments, but CHBRP is unable to quantify the amount of these contracts. The result of the state or county funding, though, is that STD testing and treatment is largely made available to the public for no out-of-pocket cost, regardless of insurance status. The point of these contracts is to reduce barriers for accessing this care, including those that insurance carriers may impose with their in-network

requirements. STD clinics would also be able to absorb increases in utilization because of this continued state and county support, as they continue to serve more of the public regardless of insurance status.

If AB 2204 were enacted, it is unlikely that these sources of state and county funding would decrease, as STD clinics would still have the job of providing services to the uninsured and to enrollees with Medi-Cal coverage. Thus, an enrollee may actually face lower out-of-pocket costs if they report being uninsured to the STD clinic, rather than going through their insurance coverage and paying any copays that may be required.

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, AB 2204 would alter requirements related to coverage of identified tests and treatments for sexually transmitted diseases (STDs). AB 2204 would define the list of STDs and the relevant tests and treatments through reference to guidelines published by the Centers for Disease Control and Prevention (CDC). AB 2204 would require group and individual plans and policies regulated by the Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI) to reimburse STD-related testing and treatment provided by "noncontracting health facilities" at in-network rates. AB 2204 would also require that enrollees be responsible only for in-network cost sharing. 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[29] of AB 2204 on testing and treatment for STDs, potential disparities, and financial burden. See the *Long-Term Impacts* section for discussion of premature death and economic loss.

Estimated Public Health Outcomes

As presented in *Medical Effectiveness*, there is clear and convincing evidence based on the 2015 CDC STDs Treatment Guidelines that the recommended tests and treatments are effective and that untreated STDs can lead to serious complications. Because CHBRP did not conduct an independent review of the medical effectiveness literature for testing and treatment for each individual STD, it is possible that the level of effectiveness for testing and treatment varies across STDs, but we were not able to conduct a literature review for each of these individually.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, approximately 33.5% of commercial/CalPERS enrollees have coverage for STD testing and treatment at out-of-network facilities,[30] and none have coverage for such out-of-network services at in-network reimbursement rates and in-network cost sharing (Table 1). Therefore, AB 2204 is expected to alter coverage for STD testing and treatment for approximately 13.4 million people. This is estimated to result in an increase in testing and related treatment by 2.5%, thus leading to testing and treatment for an additional 45,558 people (as derived from the Utilization and Cost subsection of Table 1).

Per the 2015 CDC STDs Treatment Guidelines, recommended testing and treatments for STDs relevant to this analysis promote a reduction, elimination, and/or shortened duration of related symptoms (e.g., reduction in warts); control in infection; suppression of viral replication; reduction in transmission of disease to a noninfected sexual partner; and/or cure rates of 92% to 100% based on the type of STD (e.g., receipt of recommended treatments for chlamydia can result in cure rates of 97% to 98%). Given the anticipated increase in utilization, there will be an increase in the number of individuals tested, diagnosed, and treated for STDs, and a subsequent decrease in short- and long-term health outcomes based on the type of STD.

In the first year postmandate, CHBRP estimates an additional 45,558 commercial/CalPERS enrollees with newly compliant benefit coverage would seek testing and treatment for STDs. This estimate is supported by clear and convincing evidence that there are STD tests and treatments that are medically effective and an increase in utilization (2.5%) of testing and treatment for STDs.

[29] CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.
[30] All enrollees have coverage for emergency services and services provided when they are physically out of area" for in-network providers.

Potential Harms From AB 2204

When data are available, CHBRP estimates the marginal change in relevant harms associated with interventions affected by the proposed mandate. In the case of AB 2204, there is no evidence to suggest that an increase in the use of STD testing and treatment could result in additional harm to enrollees.

Impact on Disparities[31]

Insurance benefit mandates that bring more state-regulated plans and policies to parity may change an existing disparity. As reported in the *Background* section, disparities exist by race/ethnicity; age; women and infants; and gender identity/sexual orientation (e.g., men who have sex with men and women who have sex with women). According to the CDC (2017b), disparities persist among racial and ethnic minorities (including Hispanic groups) related to rates of STDs compared to rates of STDs among Whites within the United States. Additionally, in comparison to older adults, disparities persist among sexually active adolescents (15 to 19 years of age) and young adults (20 to 24 years of age) as these individuals may be at higher risk for STD acquisition due to a combination of factors, including behavioral, biological, and cultural reasons (CDC, 2017c). Specific to women and infants, chlamydia and gonorrhea disproportionately affect women (and pregnant women), as women often present as asymptomatic during early infection (CDC, 2017d). Disparities also exist among gay/homosexual, bisexual, and other men who have sex with men (commonly referred to as men who have sex with men [MSM]) in comparison to women and men who have sex with women (CDC, 2017a). Within the first 12 months postmandate, CHBRP estimates AB 2204 would not change the previously mentioned disparities in the first 12 months postmandate.

A number of disparities in the prevalence of STDs exist in the United States; however, CHBRP found no evidence indicating differential use of coverage related to testing and treatment of STDs in different populations. Despite an estimated increase in utilization of testing and treatment of STDs, CHBRP projects no impact on disparities by race or ethnicity; age; women and infants; men who have sex with men; or women who have sex with women related to the prevalence of STDs.

Benefit Mandate Structure and Unequal Racial/Ethnic Health Impacts

AB 2204 would require compliance from the health insurance of commercial/CalPERS enrollees in CDI-regulated policies and DMHC-regulated plans but would not be applicable to the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans. As previously noted, because Medi-Cal enrollees already have coverage that is compliant with AB 2204, the exclusion of Medi-Cal enrollees from AB 2204 would not create any differential impacts by insurance type or by underlying differences in the populations enrolled in private and public plans.

[31] For details about CHBRP's methodological approach to analyzing disparities, see the *Benefit Mandate Structure and Unequal Racial/Ethnic Health Impacts* document here: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of AB 2204, 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 Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments), whereas other interventions may take years to make a measurable impact (e.g., coverage for tobacco cessation or vaccinations). When possible, CHBRP estimates the long-term effects (beyond 12 months postmandate) to the public's health that would be attributable to the mandate, including impacts on social determinants of health, premature death, and economic loss.

In the case of AB 2204 CHBRP estimates the change in utilization would increase by 2.5%; therefore, projected long-term public health impacts may include a reduction in future STD transmissions (such as a reduction in the prevalence of syphilis leading to a reduction in congenital syphilis leading to a subsequent reduction in the number of overall adverse health outcomes among both mother and infant in the long-term), and an overall reduction in downstream effects such as impact on premature death and economic loss.

Impacts on Premature Death and Economic Loss

Premature death

Premature death is often defined as death occurring before the age of 75 years (NCI, 2019).[32] In California, it is estimated that there were nearly 5,300 years of potential life lost (YPLL) per 100,000 population each year between 2015 and 2017 (CDPH, 2019b; County Health Rankings, 2019).[33] As premature death associated with STDs can occur long after acute infection, incidence rates attributed to STD infection can be hard to estimate and/or be inaccurately reported (McElligott, 2014). For example, while syphilis can result in death, other STDs, such as HPV, HIV, and Hepatitis B result can result in death due to secondary sequelae (McElligott, 2014). Moreover, genital herpes, gonococcal, and/or chlamydial infections may result in death due to pathogenic infection and/or from secondary sequelae (e.g., ectopic pregnancy) (McElligott, 2014). Although the aforementioned STDs can result in death, surveillance data can be inaccurate or underreported as a result of failing to record the prevalence of STD(s) on death certificates (McElligott, 2014). Mortality is a relevant outcome primarily for the following four specific STD(s): hepatitis B, HIV, HPV, and syphilis. The estimates of premature death due to these four STDs are provided below.

Hepatitis B

The age-adjusted mortality rate for hepatitis B in the United States was 0.46 per 100,000 persons in 2017 (CDC, 2019). Within California, 61 deaths in 2017 were attributed to hepatitis B per the CDC WONDER online database (CDC, 2020). While some acute HBV infections can resolve on their own, others can develop into chronic infection, in which approximately 1% of reported cases across the United States can lead to liver failure and/or death (CDC, 2015).

[32] For more information about CHBRP's public health methodology, see http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.
[33] The overall impact of premature death due to a particular disease can be measured in years of potential life lost prior to age 75 and summed for the population (generally referred to as "YPLL") (Gardner and Sanborn, 1990).

HIV

Because HIV is known to weaken a person's immune system by progressively depleting important cells that fight disease and infection, if left untreated, individuals with HIV that progresses to AIDS can experience severe health outcomes — which can ultimately lead to mortality — with a survival rate of up to 3 years (CDC, 2015). According to the California Department of Public Health (CDPH, 2018a), the annual number of deaths of persons with HIV infection increased from 1,774 in 2014 to 1,872 in 2018 (equal to 4.7 per 100,000 population). Note: this data on deaths of persons with diagnosed HIV infection represents all causes of death and may not be related to HIV infection (CDPH, 2018a).

HPV-associated cancers

If left untreated, HPV can increase the risk for several types of cancer that can lead to mortality, such as cervical, anal, and oropharyngeal cancers, with 100%, 91%, and 70% of all cases, respectively, attributed to HPV (CDC, 2015, 2019). In 2014, 472 deaths in California were attributed to cervical cancer—a known HPV-associated cancer. Despite this, cervical cancer mortality rates have decreased rapidly due to prevention and early detection (i.e., screening via pap test or pap smear) (ACS et al., 2017). Moreover, mortality rates stabilized among women below 50 years of age as well women above 50 years of age from 2010 to 2014 (ACS at al., 2017). In 2014, 130 deaths were attributed to anal cancer, and an additional 1,027 deaths were attributed to oropharyngeal cancers (ACS et al., 2017).

Congenital syphilis

If left untreated, syphilis can result in severe health outcomes, especially among pregnant mothers; in fact, congenital syphilis can result in miscarriage; stillbirth; premature birth or low birth weight; and/or infant death shortly after birth (CDC, 2015). According to the California Department of Public Health, of the 329 cases of congenital syphilis, 19 cases resulted in still births and three cases resulted in neonatal deaths (CDPH, 2018c).

There is clear and convincing evidence that treatment for hepatitis B, HIV, HPV, and congenital syphilis reduces the mortality rate attributed to those STDs. Therefore, it is possible that AB 2204 will lead to a reduction in premature death for the 116,504 enrollees who will newly get tested and treated for those four STDs in California, although the exact impact is unknown.

Economic loss

Economic loss associated with disease is generally presented in the literature as an estimation of the value of the YPLL in dollar amounts (i.e., valuation of a population's lost years of work over a lifetime). In addition, morbidity associated with the disease or condition of interest can also result in lost productivity by causing a worker to miss days of work due to illness or acting as a caregiver for someone else who is ill.

While there is no estimate of the economic loss associated with STDs overall, researchers have attempted to estimate the economic loss (both direct and indirect) associated with individual STDs. For example, Chesson et al. (2008), estimated the economic losses associated with cervical cancer; syphilis; congenital syphilis; chlamydia; gonorrhea; and HIV. These estimates were comprised of direct medical costs and the indirect costs related to a reduction in productivity due to premature mortality. CHBRP translated these findings on costs per case into 2020 dollars and calculated the following California-level estimates using rates of state-wide prevalence. Note: the population subject to the mandate represents only 34% of the state-wide population and may not match the demographic distribution across the state.

- For each case of syphilis, approximately $734 in direct and $144 in indirect costs would be avoided per individual case prevented. The total burden across California is estimated at $21,954,175.

- For each case of congenital syphilis, approximately $8,646 in direct and $77,526 in indirect costs would be avoided per individual case prevented. The total burden across California is estimated at $28,350,494.
- For each case of gonorrhea, approximately $440 in direct and $219 in indirect costs would be avoided per individual case prevented among females. The total burden across California for both males and females is estimated at $24,333,068.
- For each case of chlamydia, approximately $404 in direct and $190 in indirect costs would be avoided per individual case prevented among females. The total burden across California for both males and females is estimated at $89,055,987.
- For each case of HIV, approximately $254,000 in direct and $1.1 million in indirect costs would be avoided per individual case prevented. The total burden across California is estimated at $178,429,778,573.

Long-Term Utilization and Cost Impacts

Utilization Impacts

Over the long-term, increases in STD tests and treatments and HIV antiretroviral medications are known to both improve a person's health and to reduce the spread of STDs throughout the population (see Public Health Impacts above). With reduced spread of STDs, there should come a point where utilization of STD tests begins to decrease, as fewer enrollees exhibit symptoms that would lead to an STD test. With fewer cases and a lower prevalence of STDs, treatments should also have lower utilization over the long-term.

HIV antiretroviral medications, however, continue over a person's lifetime and enrollees are not expected to reduce their utilization of these medications in the long-term. But better access to HIV medications should lead to improved personal health, and result in lower use of high-cost emergency department care and an increase in Quality of Life Years (QALYs) among enrollees who are HIV positive (Farnham et al., 2013). While the increased life expectancy does dampen this effect, the overall impact of a healthier lifespan is to decrease expected use of the health care system for numerous other potential comorbidities, which cannot be quantified individually, but as a whole, lead to reduced utilization of the health care system. Additionally, as discussed in the *Medical Effectiveness* section, management of an enrollee's HIV leads to reduced infection of others (CDC, 2015), which will contribute to reduced overall utilization of HIV medications among enrollees over the long term.

Cost Impacts

With the long-term lower utilization of STD tests and treatments, the overall costs of administering these tests and treatments are also expected to decrease. But the investment in STD testing and treatments overall, as part of comprehensive family planning services, has been shown to reduce societal costs over time. A comprehensive review by Frost et al. (2014) determined that for all reproductive health services combined, the United States saved on average $7.09 for every dollar allocated to family planning services, by reducing STDs and adverse health effects, along with reductions in unwanted pregnancies. Similarly, a Return on Investment (ROI) analysis of widespread HIV testing determined that for every dollar spent, an average of $1.95 was saved due to identification and treatment of the disease (Hutchinson et al., 2012).

Over time, therefore, the costs associated with AB 2204 should reduce due to fewer STD tests and treatments, although there may be an increase in HIV antiretrovirals as enrollees live longer with the chronic condition, even with the offset savings to the health system and improved QALYs.

APPENDIX A TEXT OF BILL ANALYZED

On February 14, 2020, the California Assembly Committee on Health requested that CHBRP analyze AB 2204 that was introduced on February 12, 2020. On February 19, 2020, the Assembly Health Committee asked CHBRP to analyze proposed amended language. The version below includes the amendments.

ASSEMBLY BILL NO. 2204

Introduced by Assembly Member Arambula

February 12, 2020

An act to add Section 1367.48 to the Health and Safety Code, and to add Section 10123.92 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 2204, as amended, Arambula. Health care coverage: sexually transmitted diseases.

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 to provide coverage for preventive services, including human immunodeficiency virus testing.

This bill would require a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2021, to provide coverage for sexually transmitted disease ~~testing, treatment, and referral~~ *testing and treatment* at a contracting or noncontracting health facility at the same cost-sharing rate an enrollee or insured would pay for the same services received from a contracting health facility. The bill would require a plan or insurer to reimburse a noncontracting health facility providing sexually transmitted disease ~~testing, treatment, and referral~~ *testing and treatment* at the same rate at which it reimburses a contracting health facility for those covered services. *The bill would also require a noncontracting health facility to be licensed to provide these services.* Because a willful violation of these provisions by a health care service plan would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement. This bill would provide that no reimbursement is required by this act for a specified reason.

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

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

SECTION 1. The Legislature finds and declares the following:

(a) Sexually transmitted diseases (STDs) represent a large, persistent, and growing public health challenge for the citizens of our state.

(b) Because STDs are often asymptomatic, the burden of the disease is far greater than the number of reported cases.

(c) According to data from the federal Centers for Disease Control and Prevention (CDC), incidence rates of STDs in California have continued to increase dramatically. In the last 10 years of complete records through 2017, chlamydia rose by 47 percent. During the same period, gonorrhea increased by 192 percent, and primary and secondary syphilis tripled. At the same time, California's population grew by only 8.7 percent.
(d) The State Department of Public Health reports that the gonorrhea rate in 2017 for all Californians was 190 cases per 100,000 population; in 2013, it was 100 cases. More striking is how this disease in particular is impacting young Californians: the rate for females 15 to 19 years of age, inclusive, was 313.6 per 100,000 population and 485.9 for females 20 to 24 years of age, inclusive. For males it was 210.8 and 639.2, respectively.
(e) The problem is even more acute in communities of color. In 2017, in every age and gender group, the rate of gonorrhea in African Americans exceeded the rate in every other racial group. Among Black females 15 to 19 years of age, inclusive, the rate was more than nine times the rate among ~~white~~ *White* females in the same age range. The highest case rates were among Black males 25 to 29 years of age, inclusive (2,181.3 per 100,000), and Black females 20 to 24 years of age, inclusive (1,599.5 per 100,000).
(f) In the most tragic consequence of the STD epidemic, the cases of congenital syphilis more than tripled between 2014 and 2018, resulting in 21 infant deaths and 31 infants with complications related to syphilis.
(g) In addition, California is losing the war clinically because of the inexorable rise of drug-resistant STDs. The CDC has sounded the alarm, stating, "We are currently down to one last effective class of antibiotics" to treat gonorrhea. The CDC is beginning to see signs of resistance to this last class of antibiotic.
(h) California experienced astronomical gonorrhea rates in the 1970s and 1980s. A concerted effort to control STD rates led to a marked reduction in gonorrhea rates in the late 1990s and early 2000s.
(i) However, since 2009, we have witnessed a sharp resurgence in the rates of gonorrhea and other STDs that rival the increases in the 1960s.
(j) A major barrier to controlling the STD epidemic is the lack of access to STD testing and referral.
(k) Many people are not comfortable discussing sexual health issues with their primary care physicians and, as a result, avoid STD testing because their physicians are the only path to testing that is covered by their health care service plans or insurers.
(l) These citizens would choose to self-refer to a health facility where they can receive STD testing and referral in a safe, confidential, and nearly anonymous setting. However, unless the health facility is contracted with a person's health care service plan or insurer, the person either is ineligible to receive services at that facility or must pay out-of-network rates to receive services.
(m) Requiring STD clinics to contract with an insurer, even if only for discrete STD services, would still require patients to seek a referral to an STD clinic through the primary care physician with whom they currently choose not to discuss sexual health issues. This would do nothing to resolve the current problem: too many patients choose to skip their primary care provider and self-refer to an STD clinic.
~~(m)~~
(n) Many clinics that provide STD ~~testing, treatment, and referral~~ *testing and treatment* are forced to cease or limit services to patients who cannot afford to pay simply because the resources are anemic. For every dollar a clinic receives in public funds, the clinic is spending nearly $3 in direct services. Financially, that large discrepancy is unsustainable.
(o) At the same time, however, insurers want to be assured that an STD clinic that is providing services to the insurer's beneficiary is a qualified and quality clinic. An STD clinic should have the imprimatur of the state and the county by being licensed and receiving state or local funding for STD testing and treatment services.
(p) The federal Centers for Disease Control and Prevention have adopted and periodically review and update Sexually Transmitted Disease Treatment Guidelines. These guidelines outline comprehensively the expectations of providers in terms of testing, prevention, and clinical treatment.
~~(n)~~
(q) As long as Californians are choosing not to be tested or ignoring the need to be tested because they are not comfortable with their options, the STD epidemic in California will continue to spiral out of control. As long as state and local governments are unable or unwilling to adequately support the public health costs necessary to control the STD epidemic, the people of California will have insufficient access to basic STD testing and treatment.
~~(o)~~

(r) Therefore, the more insured persons can receive STD services even from an in-network or out-of-network provider, the more state and local public health funds can be directed to persons who are not covered for STD services.
~~(p)~~
(s) Further, California must do everything in its power to ensure that Californians have widespread access to health facilities that can provide the necessary opportunities for STD ~~testing, treatment, and referral,~~ *testing and treatment,* regardless of whether or not the facility is contracted with a person's health care service plan or insurer.

SEC. 2. Section 1367.48 is added to the Health and Safety Code, to read:

1367.48. (a) An individual or group health care service plan contract issued, amended, or renewed on or after January 1, 2021, shall provide coverage for sexually transmitted disease ~~testing, treatment, and referral~~ *testing and treatment* at the same cost-sharing rate an enrollee would pay for the same services received from a contracting health facility, regardless of whether the ~~testing, treatment, and referral~~ *testing and treatment* occurred at a contracting health facility or a noncontracting health facility.
(b) The health care service plan shall reimburse a noncontracting health facility providing sexually transmitted disease ~~testing, treatment, and referral~~ *testing and treatment* at the same rate at which it reimburses a contracting health facility for the same covered services.
(c) For purposes of this section, covered services shall be only those prescribed by the Sexually Transmitted Disease Treatment Guidelines adopted by the federal Centers for Disease Control and Prevention.
(d) A noncontracting health facility shall be licensed by the state and shall be a contractor with the state or the county in which it is located to provide clinical sexually transmitted disease services.

SEC. 3. Section 10123.92 is added to the Insurance Code, to read:

10123.92. (a) An individual or group health insurance policy issued, amended, or renewed on or after January 1, 2021, shall provide coverage for sexually transmitted disease ~~testing, treatment, and referral~~ *testing and treatment* at the same cost-sharing rate an insured would pay for the same services received from a contracting health facility, regardless of whether the ~~testing, treatment, and referral~~ *testing and treatment* occurred at a contracting health facility or a noncontracting health facility.
(b) The health insurer shall reimburse a noncontracting health facility providing sexually transmitted disease ~~testing, treatment, and referral~~ *testing and treatment* at the same rate at which it reimburses a contracting health facility for the same covered services.
(c) For purposes of this section, covered services shall be only those prescribed by the Sexually Transmitted Disease Treatment Guidelines adopted by the federal Centers for Disease Control and Prevention.
(d) A noncontracting health facility shall be licensed by the state and shall be a contractor with the state or the county in which it is located to provide clinical sexually transmitted disease services.

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 medical effectiveness literature review conducted for this report. A discussion of CHBRP's system for grading evidence, as well as lists of MeSH Terms, publication types, and keywords, follows.[34]

Studies of the effects of the informed consent process as well as general anesthesia and non-surgical treatment options were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, Business Source Complete, the Cumulative Index of Nursing and Allied Health Literature (CINAHL), and PsycINFO.

The search was limited to abstracts of studies published in English. The medical effectiveness search was limited to studies published from 2008 to present. The literature on the effectiveness of STD treatments did not include any randomized controlled trials. The majority of the papers returned were case reports or systematic reviews).

Reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria.

The literature review returned abstracts for 332 articles, of which 40 were reviewed for inclusion in this report. A total of 23 studies were included in the medical effectiveness review for AB 2643.

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.*[35] 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*

[34] The treatments and tests recommended in the 2015 CDC Treatment Guidelines are deemed to be the current gold standard with regard to testing and treatment of STD's, and further review of the literature was not required in order to evaluate the medical effectiveness of the treatments reviewed as part of this analysis.
[35] Available at: www.chbrp.org/analysis_methodology/docs/medeffect_methods_detail.pdf.

- *Inconclusive evidence; and*
- *Insufficient evidence.*

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

A grade of *inconclusive evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *insufficient* evidence indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

Public Health Search Terms and Phrases (* indicates truncation of word stem)

- Search STD/STI*Testing* Barriers
- Search STD/STI*Treatment* Barriers
- Search STD/STI*Testing* Demographic Factors Below
- Search STD/STI*Treatment* Demographic Factors Below
    - race;
    - racial disparities;
    - ethnicity;
    - gender;
    - sex differences;
    - stigma
    - education;
    - gay disparities;
    - bisexual disparities;
    - men who have sex with men disparities/MSM disparities

- Search STD/STI*Factors Below
    - premature death;
    - economic loss;
    - morbidity;
    - mortality;
    - productivity and cost of illness;

Cost Search Terms and Phrases

- price of STD/STI testing or treatment at an STD clinic;
- unit cost of STD/STI testing or treatment at an STD clinic;
- cost of STD/STI testing or treatment at an STD clinic;
- cost offset associated with STD/STI testing or treatment at an STD clinic;
- cost savings associated with STD/STI testing or treatment at an STD clinic;

- cost-effectiveness of STD/STI testing or treatment at an STD clinic;
- cost-utility associated with STD/STI testing or treatment at an STD clinic;
- utilization of STD/STI testing or treatment at an STD clinic;
- demand for STD/STI testing or treatment at an STD clinic;
- supply of STD/STI testing or treatment at an STD clinic;
- price elasticity of demand for treatment at an STD clinic

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

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as the contracted actuarial firm, Milliman, Inc.[36]

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.[37]

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

Analysis-Specific Caveats and Assumptions

This subsection discusses the caveats and assumptions relevant to specifically to an analysis AB 2204.

AB 2204 would define a list of sexually transmitted diseases (STDs) and a list of relevant treatments by reference to the CDC's "Sexually Transmitted Disease Treatment Guidelines" (The most current set of those guidelines [2015]). For these treatments for these STDs, AB 2204 would:

- Require coverage of services when provided by **noncontracting health facilities (**"clinics with state/county STD contracts") and:
    - Would require that these facilities be reimbursed at in-network rates and,
    - Would require that enrollees pay only in-network cost-sharing rates.

AB 2204 would define a "**noncontracting health facility**" as one licensed by the state and contracting with the state or the county in which it resides to provide clinical STD services. Since we received carrier responses for only two plans, we are simulating response rates for plans H21-H24 to mimic a 72% HMO population, based on data from the California HealthCare Foundation (CHCF, 2019).

This analysis focuses on the test and treatments for the most common STDs listed in the CDC guide (see Table 3 in the *Medical Effectiveness* section). Relevant codes from the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) and the AMA CPT® (Common Procedure Terminology) were used to extract data from Milliman's 2017 Consolidated Health Cost Guidelines Sources Database (CHSD) and 2017 MarketScan® Commercial Claims and Encounters Database. These data were used to develop baseline cost and utilization information for HIV Medication and STD Services. Baseline cost and utilization rates per 1,000 members were calculated and used to estimate the number of treatments and average cost per service.

For this analysis, CHBRP identified a set of diagnosis codes and procedure codes associated with STD testing and treatment services with assistance from a medical coder using the AMA CPT® and the ICD-10-CM.

The diagnosis codes associated with STD treatment covered by AB 2204 are shown in Table 5:

[36] CHBRP's authorizing statute, available at http://chbrp.com/CHBRP authorizing statute_2018_FINAL.pdf, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
[37] See method documents posted at http://chbrp.com/analysis_methodology/cost_impact_analysis.php; in particular, see *2019 Cost Analyses: Data Sources, Caveats, and Assumptions*.

Table 5. Diagnosis Codes Used for STD ServicesDiagnosis Code (ICD-10)	Description
A50	Congenital syphilis
A51	Early syphilis
A52	Late syphilis
A53	Other and unspecified syphilis
A54	Gonococcal infection
A55	Chlamydial lymphogranuloma (venereum)
A56	Other sexually transmitted chlamydial diseases
A59	Trichomoniasis
A60	Anogenital herpesviral [herpes simplex] infections
A63	Other predominantly sexually transmitted diseases
A64	Unspecified sexually transmitted disease
B20	HIV
B18.0, B18.1, B19.10	Hepatitis B
B85.3	Phthiriasis
Z11.3	STD screening
Z11.4	HIV screening
Z11.51	HPV screening

Source: California Health Benefits Review Program, 2020.

CHBRP limited the services in the claims data (by service line and by disease) to services that match a list of specified STD services relevant to AB 2204 including testing, lab services, office visits, urgent care visits, and preventative exams. Minor surgeries for HPV were also included. Milliman used the Milliman Health Cost Guidelines – Grouper software to identify claims that fell into these service categories.

In addition to medical claims, CHBRP calculated the average cost for prescription medication treatment of each treatable disease from pharmacy claims. Then, using the state-wide incidence rate from CHBRP's Public Health team for each disease or the utilization rate of specified drugs, CHBRP determined the total estimated prescription medication cost and utilization rate for each pharmaceutical treatment.

- For STDs that require maintenance medication including HIV, HSV, and HPV, CHBRP estimated the total cost and utilization of medication required to treat the disease over the course of a year of treatment.
- For STDs that can be cured in a course of treatment following diagnosis, CHBRP estimated the total cost and utilization of medication required to cure the disease.

CHBRP identified all individuals utilizing STD services throughout the year to establish a baseline estimate of the number of diagnosed individuals receiving such services.

To identify HIV medications (antiretrovirals), CHBRP relied on Medi-Span® Therapeutic Classification System to include all medications identified in the class "Antiretrovirals." However, several medications were removed if they are commonly used to treat hepatitis B or used as PrEP/PEP for HIV, which is not covered under AB 2204.

Medical services unit costs were trended at an annual rate of 2.0% from 2017 to 2021. Prescription drugs were trended at a rate of 0.5% for generic drugs and 6.5% for brand-name drugs.

CHBRP assumed that payers would receive the benefit of pharmaceutical rebates for prescription drugs.

CHBRP does not have claims or other data available specifying the rate of "self-pay" or "sliding scale" payments for STD services. Literature indicates that many utilizers of STD services may not report insurance coverage when receiving services due to stigma. These services may be provided under a self-pay, sliding scale basis from safety-net clinics considered by the bill as "noncontracting health facilities". Many utilizers may not report insurance coverage because the services are offered for free. Therefore, using content matter expertise and available literature, CHBRP estimated the proportion of self-pay services not reported to insurance carriers for STD services.

Table 4 shows the utilization assumptions that underlie the AB 2204 Cost and Coverage Model, which were developed in consultation with the content expert.[38] These percentages, when applied to the enrollee population, estimated the enrollee population change in utilizing STD test and treatment services using in-network providers, out-of-network clinics, or self-pay.

Table 6. Utilization Assumptions Within the Cost and Coverage Model

Assumption	Percentage
% of current OON HIV drugs that occur at a "noncontracting health care facility"*	0.00%
% of current OON STD services that occur at a "noncontracting health care facility"*	40.00%
% Self-pay / (INN + OON + self-pay) HIV drugs	0.00%
% Self-pay / (INN + OON + self-pay) STD services	25.00%
Increase in HIV drugs (factor)	0.00%
Increase in all STD services (factor)	2.50%
Shift INN to OON HIV drugs (factor)	3.00%
Shift INN to OON STD services (factor)	3.00%
Shift in Self-pay to OON HIV drugs (factor)	0.00%
Shift in Self-pay to OON STD services (factor)	0.63%

Source: California Health Benefits Review Program, 2020.

Notes: *The exact number of out-of-network clinics that have state-funded contracts in California is unknown. CHBRP therefore assumed, after consultation with the content expert, that 40% of enrollees who currently use any out-of-network provider for tests and treatments for the most common STDs obtain those services at a clinic with state-funded contracts. This 40% of current out-of-network services would therefore represent the services potentially impacted by AB 2204.

Key: OON = out-of-network; STD = sexually transmitted disease

[38] Personal communication with Dr. Tri Do, adjunct assistant professor at UCSF, on March 10, 2020.

Determining Public Demand for the Proposed Mandate

This subsection discusses public demand for the benefits AB 2204 would mandate. Considering the criteria specified by CHBRP's authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

- 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 unions currently do not include cost-sharing arrangements for description treatment or service. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS currently have the largest number of enrollees. The CalPERS PPOs currently provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask carriers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

Second Year Impacts on Benefit Coverage, Utilization, and Cost

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of AB 2204 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 2204 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.

APPENDIX D OTHER SEXUALLY TRANSMITTED DISEASES

Other STDs Not Included in CHBRP Analysis

Although included in the 2015 CDC STD Treatment Guidelines, the 12 following STDs have been excluded from CHBRP analysis for various reasons such as rarity of disease occurrence within the United States (e.g., granuloma inguinale); alternative methods for disease transmission not exclusively attributed to sexual activity with an infected partner (e.g., Hepatitis A is primarily transmitted by the fecal-oral route); and lack of FDA-approved diagnostic tests to determine diagnosis (e.g., mycoplasma genitalium). A description of the full rationale for why CHBRP excluded each individual STD is listed below.

- **Cervicitis**: Defined as inflammation of the cervix, cervicitis can present as a symptom of gonorrhea and/or trachomatis; therefore, CHBRP is not evaluating cervicitis on its own given that it can also present as a secondary symptom of other STDs.
- **Chancroid**: Characterized as a genital ulceration and inflammation of the inguinal adenopathy, chancroid has continued to decline, with only five diagnosed cases in California in 2018. As most laboratories do not have the necessary culture media to properly identify the associated bacteria (i.e., *Haemophilus ducreyi*), CHBRP is not evaluating Chancroid.
- **Epididymitis**: Characterized as pain, swelling, and inflammation of the epididymis, epididymitis can also be a symptom of gonorrhea and/or trachomatis; therefore, CHBRP is not evaluating epididymitis on its own given that it can also present as a secondary symptom of other STDs.
- **Granuloma Inguinale**: Defined as a genital ulceration disease, this disease rarely occurs in the United States. As no FDA-approved diagnostic test for the detection of *K. granulomatis* currently exists, CHBRP is not evaluating this disease.
- **Hepatitis A**: Hepatitis A is an acute virus that is primarily transmitted by the fecal-oral route via person to person to contact or through consumption of tainted water or food. While Hepatitis A can be transmitted via sexual activity, the main method of transmission is through the fecal-oral route; therefore; CHBRP is not including an evaluation of Hepatitis A.
- **Hepatitis C**: Hepatitis C is a chronic virus that is primarily transmitted through use of shared drug-injection needles and related paraphernalia. Although Hepatitis C is transmissible through sexual contact, studies have demonstrated that transmission through sexual activity is largely inefficient; therefore, CHBRP is not evaluating Hepatitis C.
- **Lymphogranuloma Venereum (LGV):** LGV is a disease caused by three distinct strains of chlamydia trachomatis; therefore, CHBRP is not evaluating LGV on its own given that it can also present as a secondary symptom of other STDs.
- **Mycoplasma Genitalium**: Known to cause male urethritis (i.e., inflammation of the urethra), there is no FDA-approved diagnostic test for the detection of *M. genitalium*; therefore, CHBRP is not evaluating this disease.
- **Nongonoccal Urethritis (NGU)**: Defined as urethral inflammation not due to infection with *N. gonorrhoeae*, NGU can stem from a variety of etiologies and can co-occur with chlamydia and gonorrhea. Given its nonspecific diagnosis, CHBRP is not evaluating this disease.
- **Pelvic Inflammatory Disease (PID)**: PID can be characterized as a spectrum of inflammatory disorders within the upper female genital tract. As PID can present as a symptom of gonorrhea and

trachomatis, CHBRP is not evaluating PID on its own given that it can also present as a secondary symptom of other STDs.

- **Proctitis, Proctocolitis, and Enteritis (PPE):** Defined as sexually transmitted gastrointestinal syndromes, these three syndromes can also be a symptom of gonorrhea, trichomoniasis, HSV (i.e., genital herpes simplex), or syphilis. Given that it can also present as a secondary symptom of other STDs, CHBRP is not evaluating PPE.
- **Vulvovaginal Candidiasis (VC)**: VC is a yeast infection characterized by vaginal soreness and abnormal vaginal discharge among other related symptoms. As VC is not sexually transmitted, CHBRP is not evaluating this disease.
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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.

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

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