CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

EXECUTIVE SUMMARY:
Analysis of Assembly Bill 1774
Health Care Coverage:
Gynecological Cancer Screening Tests

A Report to the 2007–2008 California Legislature
April 7, 2008

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California Health Benefits Review Program Analysis of Assembly Bill 1774:
Health Care Coverage: Gynecological Cancer Screening Tests

The California Legislature requested the California Health Benefits Review program (CHBRP) to conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 1774 Health Care Coverage: Gynecological Cancer Screening Tests, as amended on March 5, 2008. This bill would mandate coverage of "any test necessary for the screening and diagnosis of gynecological cancers when ordered by a physician, nurse practitioner, or certified nurse midwife in whose judgment the test would assist or facilitate the diagnosis of cancer." AB 1774 would add Section 1367.655 to the Health and Safety Code, and Section 10123.182 to the Insurance Code.

Gynecological cancers are cancers of the female reproductive tract, including the cervix, endometrium, fallopian tubes, ovaries, uterus, vagina, and vulva. The three most common types of cancer—uterine or endometrial, ovarian, and cervical—account for 90% of all gynecological cancers.

AB 1774 is intended to address the problem of late diagnoses, when these cancers in particular are far less treatable. According to a recent press release from the bill author Assemblymember Sally Lieber, "the common Pap test does not detect ovarian or uterine cancer. Additional tests are readily available to diagnose them, but they are underutilized."

Current law requires health plans and insurers to cover all generally medically accepted cancer screening tests; an annual cervical cancer screening test, including the conventional Pap test and the human papillomavirus (HPV) screening test; and diagnostic services.

Health plans and health insurers cover gynecological cancer screening tests for women subject to their medical necessity criteria. The standards used by plans to determine medical necessity appear to be broadly consistent with evidence-based clinical guidelines issued by the U.S. Preventive Services Task Force and American Cancer Society.

CHBRP initially assumed the bill, modeled on the current cervical cancer statute, would be interpreted by regulatory agencies as preserving the right of insurers to determine medical necessity prior to authorizing services. However, discussions with state regulators and state and federal agencies that administer publicly financed health insurance programs did not support this interpretation.

Because the bill has no precedent in current law, both the Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI) view the phrase "in whose judgment" as reflecting a legislative intent to move discretion over whether a test is needed, and therefore a covered benefit, from the health plan and insurer to the individual medical providers. State and federal agencies that administer programs for Medi-Cal, Managed Risk Medical Insurance Board programs. and the California Public Employees' Retirement System (CalPERS) were also consulted, and their interpretation of the bill was consistent with those of the regulatory agencies. Conversations with the bill author staff also indicated it was the bill author's intent to allow health care providers to use their judgment and not be "second-guessed" by health

plans.[1] Consultations with legal counsel suggested that the interpretation of the bill language would end up being adjudicated in the courts. CHBRP assumes for the sake of this analysis that under AB 1774, screening would be "medically necessary" for a woman if a provider made that determination. It is possible that, following enactment of this legislation, there would be litigation over this matter, and courts might rule that the bill language does not preclude health plans and health insurers from applying medical necessity criteria for making coverage determinations. In this event, the resulting costs would be different from CHBRP cost estimates.

Medical Effectiveness

The medical effectiveness review for AB 1774 focused on the three gynecological cancers that account for 90% of all gynecological cancers in California: cervical cancer, ovarian cancer, and endometrial cancer.

Cervical Cancer

Screening Asymptomatic Women at Average Risk (no previous history of abnormal cervical cytology or cervical lesions)

- There is a preponderance of evidence that, among asymptomatic women who are sexually active and have not had a hysterectomy, screening with conventional cytology (i.e., Pap test) reduces the incidence of cervical cancer, because this test can detect precancerous lesions. Treatment of precancerous lesions can prevent a woman from developing cervical cancer. In addition, conventional cytology can reduce morbidity and mortality from cervical cancer by detecting cancerous lesions at an early stage at which treatment is most likely to be successful.

- A preponderance of the evidence suggests that liquid-based cytology is no more accurate than conventional cytology for screening asymptomatic women for cervical cancer, regardless of whether it is performed alone or in conjunction with DNA testing for the human papillomavirus (HPV).

- The evidence of the accuracy of the following tests for screening asymptomatic women for cervical cancer relative to conventional cytology is ambiguous:

    - HPV DNA test versus conventional cytology
    - Multimodal screening with the HPV DNA test and conventional cytology versus conventional cytology alone

[1] Personal communication with Barry Steinhart, Office of Assemblymember Lieber, February 12, 2008.

Screening Asymptomatic Women at High Risk (due to abnormal cytology and/or previous history of cervical lesions)

- The available evidence suggests that the HPV DNA test and conventional cytology are equally accurate for identifying women with abnormal cytology (i.e., abnormal Pap test) who should undergo further testing with colposcopy (and biopsy if necessary) to determine whether they have cervical cancer or precancerous lesions.

- The evidence of relative accuracy of the following tests and technologies for identifying women with abnormal cytology who should receive further testing is ambiguous:

    - Liquid-based cytology versus conventional cytology
    - HPV DNA test plus conventional cytology versus conventional cytology alone

- The preponderance of evidence suggests that using the HPV DNA test to triage women with abnormal cytology on either an initial or a repeat test more accurately identifies women who need further testing than performing conventional cytology alone.

Ovarian Cancer

Screening Asymptomatic Women at Average Risk (no familial risk history)

- There is insufficient evidence to determine the effectiveness of providing genetic tests for mutations associated with increased risk of ovarian cancer (i.e., *BRCA1* and *BRCA2* mutations) to women who do not have a family history (i.e., hereditary risk) of ovarian cancer.

- The preponderance of evidence suggests that screening asymptomatic women at average risk for ovarian cancer with transvaginal ultrasound and/or the CA-125 blood test can detect ovarian cancer at an earlier stage.

- However, there is insufficient evidence to determine whether screening asymptomatic women at average risk for ovarian cancer reduces morbidity and mortality over the long term.

- Screening asymptomatic women at average risk for ovarian cancer might increase harms due to surgery and complications thereof.

Screening Asymptomatic Women at High Risk (with familial risk history)

- The available evidence suggests that, among asymptomatic women at increased risk for ovarian cancer due to age and/or family history of ovarian cancer, annual screening with transvaginal ultrasound is accurate and may increase survival over the short term.

- There is insufficient evidence to determine whether multimodal screening of asymptomatic women with a family history of ovarian cancer using transvaginal ultrasound and CA-125 yields more accurate results than screening with transvaginal ultrasound alone.

Endometrial Cancer

Screening Asymptomatic Women at Average Risk (those not presenting with abnormal uterine bleeding)

- No studies of the effectiveness of screening asymptomatic women for endometrial cancer were identified.

Diagnosing Women With Symptoms That May Indicate Cancer (those presenting with abnormal uterine bleeding)

- There is insufficient evidence to determine whether pelvic or transvaginal ultrasound can accurately diagnose endometrial hyperplasia or carcinoma among women with abnormal uterine bleeding.

- The preponderance of evidence suggests that endometrial biopsy and hysteroscopy can accurately diagnose endometrial carcinoma among women with abnormal uterine bleeding.

Utilization, Cost, and Coverage Impacts

Summarized below is one set of estimates of possible utilization and cost effects using assumptions based on the judgment of expert physician consultants, opinions solicited from physicians in community-based practice, and relevant literature.

As mentioned, CHBRP is following the opinion of the legal counsel and regulatory agencies in interpreting AB 1774 as removing the carrier's ability to apply medical necessity requirements in their coverage determinations for gynecological cancer diagnostic and screening tests. Public programs subject to AB 1774, such as Medi-Cal managed care, would also lose their ability to deny coverage for tests based on medical necessity criteria. Because CHBRP cannot project the *actual* changes in utilization that would result from prohibiting health plans from applying medical necessity guidelines for coverage determinations, estimates are provided instead for one plausible scenario that *might* occur if the bill were to pass.

CHBRP emphasizes that the utilization and cost figures presented in this report are merely an illustration of what could happen as a result of the passage of the bill, not a projection of what will happen. The impact of AB 1774 on utilization could vary substantially, depending on a number of factors that include patient demand in conjunction with provider financial incentives and competitive market pressures. Furthermore, if carriers mounted a successful court challenge to the interpretation of the bill that re-established their legal authority to include medical necessity requirements in their coverage determinations, utilization in the long run would be unlikely to change as a result of the bill, since carriers are generally already covering all medically appropriate tests.

Coverage

- CHBRP's cost analysis focuses on women 18 years and older because children under 18 are unlikely to be screened for gynecological cancer. CHBRP estimates that 8,433,000 females aged 18 and over are currently covered by health plans that would be subject to AB 1774.

- Based on its survey of major California health plans, CHBRP estimates that 100% of privately and publicly insured 18- to 64-year-old females currently have coverage for screening and diagnostic tests for gynecological cancers, subject to medical necessity requirements of the health plans.

- Tests currently being covered by health plans include diagnostic tests for symptomatic women and screening tests for asymptomatic women for which there is evidence of medical effectiveness (for example, those recommended by the U.S. Preventive Services Task Force and the American Cancer Society).

- With the exception of Pap tests for all women and HPV DNA tests for women of certain ages, privately as well as publicly funded health plans do not generally cover screening tests for average-risk, asymptomatic women, with the stated reason that there is no evidence of medical effectiveness for these tests. Health plans generally cover the screening tests recommended for high-risk, asymptomatic women.

Utilization

- As diagnostic tests, screening tests for certain high-risk, asymptomatic women, Pap tests for all women and HPV DNA tests for women of certain ages are already covered, the impact of AB 1774 on utilization would likely be limited to other gynecological cancer screening tests for average-risk, asymptomatic women.

- In the scenario modeled in this analysis, CHBRP assumed use of "first-line" screening tests ranged from 0% to 40%, depending on the test and subpopulation. Under this scenario, utilization of screening tests in the first year post-mandate would increase by about 1,565,000 for transvaginal ultrasound, 945,000 for endometrial biopsy, 232,000 for *BRCA1/2* genetic mutation tests, and 244,000 for HNPCC genetic mutation tests. Other selected screening tests would experience lower utilization increases.

- Because each woman would need to have genetic testing only once in her lifetime, utilization of these tests would likely diminish significantly in the years following the bill's passage as more of the population underwent such testing. Eventually demand for these tests among adult women would be satisfied and only subsequent cohorts of girls turning 18 would require new testing.

Costs

- Based on the assumed utilization increases in the scenario being modeled, total annual health care expenditures (including total premiums and out-of-pocket expenditures) could increase by $2.72 billion, or 3.43%, as a result of AB 1774.

- The estimates presented for this scenario do not include the cost of surgical complications resulting from false-positive screens that lead to unnecessary surgery; however, these costs are not anticipated to have a material impact on the overall cost of the bill.

- The estimates also exclude potential savings due to earlier diagnosis. Based on the medical effectiveness literature, early detection associated with screening tests not already covered would be relatively rare and limited to ovarian cancer.

- Over half of the potential increase in costs is driven by the assumed use of genetic testing for endometrial and ovarian cancers, as the cost model assumes that approximately 3% of all women would receive these tests in the first year post-mandate and the tests cost $2,300-$3,300 each. The cost of this genetic testing would likely diminish substantially over time, as fewer women remain who have never been tested. About one-seventh of the cost is attributable to dilation and curettage surgery for women whose endometrial biopsies were inconclusive or otherwise required follow-up. Over one-quarter of the cost is due to transvaginal ultrasound screening and follow-up for false positives.

- CHBRP estimates that under the scenario presented in the cost section, total premiums paid by all private employers in California could increase by about $1.63 billion per year, or 3.46%.

- Total premiums for individually purchased insurance could increase by about $287 million, or 4.67%. The share of premiums paid by individuals for group or public insurance could increase by $437 million, or 3.41%.

- Premiums paid by CalPERS could increase by about $91 million, or 3.09%. Medi-Cal expenditures could increase by $77 million, or 1.90%. Healthy Families is not expected to experience an increase in costs.

- Individual out-of-pocket expenditures could increase by $202 million, or 3.60%. The extent to which this increase would be offset by a decrease in expenditures for screening tests currently paid entirely out of pocket is unknown; however, it is unlikely that large numbers of women are currently receiving noncovered gynecological cancer screening tests because these tests are generally expensive and their use for asymptomatic, average-risk women is not recommended by any national medical organization.

- Based on the scenario being modeled, CHBRP estimates that across all markets, approximately 82,000 commercially insured individuals could lose coverage due to the premium increases resulting from the mandate.

- There is a dearth of evidence with regard to the cost effectiveness of gynecological cancer screening tests for average-risk, asymptomatic women, but it seems unlikely that general population screening using tests currently not covered would be cost effective when medical effectiveness has not yet been demonstrated.

Public Health Impacts

- The positive health outcomes intended by AB 1774 are those associated with the detection of gynecological cancers at an earlier stage, primarily increased survival and decreased morbidity due to early treatment. Another positive outcome is the reduction in stress and anxiety related to gynecological cancers for those who receive reassuring results.

- There are also potential harms associated with AB 1774. False-positive results generate unnecessary stress and anxiety, and result in complications from follow-up procedures. Additionally, false negatives could result in delayed treatment once symptoms emerge.

- Based on the scenario for increased utilization, no cases of cervical cancer are expected to be detected early due to increased HPV DNA testing among women 18–29 years old. However, approximately 4,600 women are expected to have false-positive results, which could result in stress and anxiety.

- Based on the scenario for increased utilization, ovarian cancer screening of the average-risk population due to AB 1774 is expected to result in the detection of early-stage cancer for 470 women over 3 years. More than 30,000 women are expected to have false-positive results for the initial screen, and another 6,600 women are expected to have unnecessary surgeries due to increased screenings. Of the 6,600 unnecessary surgeries, approximately 330 are expected to have complications, such as hemorrhage and infection.

- Since no studies were found to discuss the accuracy or effects of endometrial cancer tests for asymptomatic women, the health effects of the estimated increase in utilization of tests for endometrial cancer are unknown.

- Since AB 1774 is not expected to result in increased utilization of proven medically effective gynecological screening and diagnostic tests where racial disparities exist, it is not expected to have an impact on racial disparities related to gynecological cancers.

- Since insurers typically cover the gynecological tests that have been found to be medically effective, AB 1774 is not expected to substantially reduce premature death among women. However, for the 470 women expected to have early-stage ovarian cancer detected due to AB 1774, this could potentially improve survival.

- Overall, at present, there are over $500 million in indirect costs associated with gynecological cancers in California. AB 1774 could potentially decrease lost productivity costs by increasing survival for women with earlier detected ovarian cancer. There could also be some lost productivity costs associated with false positives and the time necessary to get follow-up tests and procedures; particularly for the estimated 330 women projected to have complications from surgery.

- Based on the scenario that approximately 82,000 people could lose coverage due to increased premiums associated with AB 1774, there are potential long-term health impacts associated with the loss of insurance. In California, uninsured individuals report poorer health, more psychological distress, and more delays in receiving treatments.

Table 1. Summary of Coverage and Potential Utilization and Cost Impacts of AB 1774

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Coverage				
Number of individuals affected by mandate—women aged 18–64 yrs	8,433,000	8,433,000	—	0%
Percentage of individuals with coverage for cervical cancer tests				
Diagnostic testing for symptomatic women	100%	100%	0%	0%
Routine screening tests for high-risk, asymptomatic women	100%	100%	0%	0%
Routine screening tests for average-risk, asymptomatic women	100%	100%	0%	0%
Percentage of individuals with coverage for ovarian cancer tests				
Diagnostic testing for symptomatic women	100%	100%	0%	0%
Routine screening tests for high-risk, asymptomatic women	100%	100%	0%	0%
Routine screening tests for average-risk, asymptomatic women	0%	100%	100%	N/A
Percentage of individuals with coverage for endometrial cancer tests				
Diagnostic testing for symptomatic women	100%	100%	0%	0%
Routine screening tests for high-risk, asymptomatic women	100%	100%	0%	0%
Routine screening tests for average-risk, asymptomatic women	0%	100%	100%	N/A
Utilization and cost				
Number of tests/procedures used by average-risk, asymptomatic women				
Pap smears	792,000	792,000	—	0%
HPV DNA test	83,000	311,000	228,000	275%
Colposcopy	—	8,000	8,000	N/A
Transvaginal ultrasound	—	1,565,000	1,565,000	N/A
CA-125 blood test	—	175,000	175,000	N/A
Laparoscopy	—	6,000	6,000	N/A
Laparotomy	—	2,000	2,000	N/A
BRCA1/2 genetic test	—	232,000	232,000	N/A
BRCA1/2 genetic test—genetic counseling	—	232,000	232,000	N/A
Endometrial biopsy	—	945,000	945,000	N/A
Dilation and curettage	—	71,000	71,000	N/A
HNPCC genetic test	—	244,000	244,000	N/A
HNPCC genetic test—genetic counseling	—	244,000	244,000	N/A

Table 1. Summary of Coverage and Potential Utilization and Cost Impacts of AB 1774 (Cont'd)

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Average cost per test/procedure, selected tests/procedures				
Pap tests	$41.12	$41.12	—	0%
HPV DNA test	$68.80	$68.80	—	0%
Colposcopy	$235.05	$235.05	—	0%
Transvaginal ultrasound	$363.14	$363.14	—	0%
CA-125 blood test	$45.14	$45.14	—	0%
Laparoscopy	$3,667.16	$3,667.16	—	0%
Laparotomy	$3,010.29	$3,010.29	—	0%
BRCA1/2 genetic test	$3,292.02	$3,292.02	—	0%
BRCA1/2 genetic test—genetic counseling	$42.27	$42.27	—	0%
Endometrial biopsy	$164.31	$164.31	—	0%
Dilation and curettage	$2,788.57	$2,788.57	—	0%
HNPCC genetic test	$2,298.70	$2,298.70	—	0%
HNPCC genetic test—genetic counseling	$42.27	$42.27	—	0%
Expenditures				
Premium expenditures by private employers for group insurance	$47,088,966,000	$48,717,926,000	$1,628,960,000	3.46%
Premium expenditures for individually purchased insurance	$6,158,288,000	$6,445,780,000	$287,492,000	4.67%
Premium expenditures by individuals with group insurance, CalPERS, Healthy Families, AIM or MRMIP	$12,819,308,000	$13,256,253,000	$436,945,000	3.41%
CalPERS employer expenditures[a]	$2,942,984,000	$3,033,831,000	$90,847,000	3.09%
Medi-Cal state expenditures[b]	$4,044,192,000	$4,121,111,000	$76,919,000	1.90%
Healthy Families state expenditures[c]	$644,074,000	$644,074,000	$0	0.00%
Individual out-of-pocket expenditures (deductibles, copayments, etc.)	$5,602,060,000	$5,803,857,000	$201,797,000	3.60%
Out-of-pocket expenditures for non-covered services	N/A	N/A	N/A	N/A
Total annual expenditures[e]	$79,299,872,000	$82,022,832,000	$2,722,960,000	3.43%

Source: California Health Benefits Review Program, 2008.
Notes: The population includes employees and dependents covered by employer-sponsored insurance (including CalPERS), individually purchased insurance, and public health insurance provided by a health plan subject to the requirements of the Knox-Keene Health Care Service Plan Act of 1975. All population figures include enrollees aged 0–64 years and enrollees 65 years or older covered by employer-sponsored insurance. Premium expenditures by individuals include employee contributions to employer-sponsored health insurance and member contributions to public health insurance.
[a]Of the CalPERS employer expenditure, about 60% of the increase, or $54,508,000, would be State expenditures for CalPERS members who are State employees.
[b]Medi-Cal state expenditures for members under 65 years of age include expenditures for Major Risk Medical Insurance Program (MRMIP) and Access for Infants and Mothers (AIM) program.
[c]CHBRP assumes that utilization and cost impacts will be negligible for Healthy Families. Only 2% of Healthy Families enrollees are women aged 18 years and above, and even those enrollees are 18- and 19-year-olds.
This includes administrative expenses of $11,324,000,000 before mandate and $11,723,000,000 after the mandate, an increase of $399,000,000.
Key: CalPERS=California Public Employees' Retirement System.

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CHBRP gratefully acknowledges all of these contributions but assumes full responsibility for all of the report and its contents. Please direct any questions concerning this report to:

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A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP **Faculty Task Force** comprises rotating representatives from six University of California (UC) campuses and three private universities in California. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts 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 coordinates all external communications, including those with the California Legislature. The level of involvement of members of the CHBRP Faculty Task Force and staff varies on each report, with individual participants more closely involved in the preparation of some reports and less involved in others.

As required by the CHBRP authorizing legislation, UC contracts with a certified actuary, Milliman Inc. (Milliman), to assist in assessing the financial impact of each benefit mandate bill. Milliman also helped with the initial development of CHBRP methods for assessing that impact.

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 and thoughtful critiques provided by the members of the National Advisory Council. However, the Council does not necessarily approve or disapprove of or endorse this report. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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