CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

EXECUTIVE SUMMARY
Analysis of Senate Bill 161 Health Care Coverage: Chemotherapy Treatment

A Report to the 2009-2010 California Legislature
April 17, 2009
Revised June 26, 2009

CHBRP 09-07

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Revision: a misprint was corrected. Estimates of postmandate, out-of-pocket expenditures presented on p.34 were corrected to match the accurate figures already present in Table 1.

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Suggested Citation:

California Health Benefits Review Program (CHBRP). (2009). *Analysis of Senate Bill 161: Health Care Coverage: Chemotherapy Treatment.* Report to California State Legislature. Oakland, CA: CHBRP. 09-07.

EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Senate Bill 161, Health Care Coverage: Chemotherapy Treatment

The California Senate Committee on Health requested on February 13, 2009, that the California Health Benefits Review Program (CHBRP) conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 161. In response to this request, CHBRP undertook this analysis pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as codified in Section 127600, et seq. of the California Health and Safety Code.

SB 161 places requirements on health insurance policies regulated by the California Department of Insurance (CDI) and health plans regulated by the Department of Managed Health Care (DMHC). For both plans and policies that provide coverage for chemotherapy treatments, the bill would mandate that coverage for orally administered anticancer medications be provided on a basis no less favorable than coverage provided for injected or intravenously administered anticancer medications. The bill specifically addresses "medication used to kill or slow the growth of cancerous cells." Therefore, the mandate would not impact coverage for other drugs commonly prescribed to cancer patients, such as antipain, antidiarrhea, or antinausea medications.

Health plans and insurers apply a variety of administration and utilization management strategies to covered benefits to promote appropriate utilization and to control costs. Common strategies include provisions for cost sharing with members or enrollees. Requiring prior authorization, developing clinical guidelines, or covering only medications listed in a formulary are examples of other strategies. The exact set of provisions applicable to a person's coverage depends upon the contract or policy he or she has with a plan or insurer. Adding to the complexity of the situation, there is a great deal of variation in contracts and policies, even among those issued by a single plan or insurer. The bill's phrase "no less favorable" could apply to all utilization management strategies. However, in order to complete its analysis within the specified 60-day timeframe, CHBRP has made the simplifying assumption that coverage is already "no less favorable" for all aspects of benefits administration and utilization management except cost sharing.

Cost sharing provisions require members or enrollees to pay some portion of expenses. Common cost sharing provisions include deductibles, coinsurance, and copayments, but the provisions applicable to a person's coverage depend on his or her contract or policy. Cost sharing for medications is frequently complicated by tiered pricing. A plan or insurer may assign drugs to tiers (generic drugs in the lowest, and very expensive drugs in the highest) and apply varying copayments and coinsurance rates to different tiers. As with cost sharing in general, the impact of tiers (if any) depends on the specifics of a person's contract or policy.

In most instances, oral anticancer medications are subject to pharmacy plan patient cost sharing provisions, often a flat-dollar copayment per prescription. In some instances, the copayment may be coupled with a deductible. Intravenous and injectable anticancer medications delivered

outside a hospital setting are generally covered as part of a physician office visit. Medical benefit cost sharing may involve copayments or a percentage coinsurance. In some instances, either may be coupled with a deductible.

Cost sharing provisions vary widely by contract/policy, and the mandate only requires "coverage no less favorable" within a contract or policy, but does not require all contracts or policies to meet any one standard. For the purposes of this analysis, CHBRP assumes that health plans and insurers would comply with the mandate by reviewing the percentage cost share applied to oral anticancer medications and to intravenous/injected anticancer medication, then applying the lower of the two as the cost sharing provision for oral anticancer medications. In many cases, such a practice would lower patient out-of-pocket costs for oral anticancer medications.

The bill's phrase "no less favorable than" is vague, and so plans and insurers might comply with the mandate in ways contrary to the assumptions modeled in this report. For example, a plan or insurer could issue a contract or policy in which coinsurance (after any applicable deductible has been met) is the standard form of cost sharing for all anticancer medication. Such compliance would be "no less favorable," but would, in many instances, increase patient out-of-pocket costs for oral anticancer medications (which may previously have been subject only to a fixed-dollar copay). The estimates resulting from these assumptions therefore represent an upper bound in terms of cost for carriers.

Alternative compliance on the part of plans and insurers could lead to cost, utilization, and public health impacts different from those shown in this report.

Medical Effectiveness

Analysis approach: SB 161 would apply to such a large number of medications for such a wide range of cancers that a systematic review of the literature on the effectiveness of all of them was not feasible during the 60 days within which CHBRP must complete its reports. Instead, CHBRP reviewed the literature on orally administered anticancer medications generally and described the most widely utilized and most costly oral anticancer medications prescribed to Californians.

- All oral anticancer medications must be approved by the U.S. Federal Drug Administration (FDA) before they can be marketed or sold in the United States.
- To date, the FDA has approved 38 oral anticancer medications that are used to treat 52 different types of cancer.
- Oral anticancer medications have been available for decades, but the number of such medications has grown dramatically over the past decade, and more oral anticancer medications are being developed. Experts estimate that 100 oral anticancer medications are currently under development.

- Oral anticancer medications can be divided into three main types of medications:
  - Cytotoxic agents
  - Targeted agents
  - Hormones

- The roles of oral anticancer medications in cancer treatment vary and include:
  - Prevention of cancer recurrence in persons treated for early stage disease
  - First-line treatment to prevent growth of cancer cells
  - Second-line treatment of cancers that do not respond to first-line treatments
  - Presurgical treatment
  - Postsurgical treatment
  - Treatment of early stage cancers
  - Treatment of advanced or metastatic cancers
  - Treatment of recurrent cancers
  - Treatment of cancers that cannot be surgically removed

- Oral anticancer medications are used alone or in combination with other oral, intravenous, or injected anticancer medications, depending on the cancer they are being used treat.

- For many oral anticancer medications, there are no intravenous or injected substitutes (and vice versa). However, there are some important exceptions such as Xeloda, Temodar, and methotrexate sodium.

- The most frequently prescribed oral anticancer medications in California in 2006 were three hormone drugs (Arimidex, tamoxifen citrate, and Femara) that are used to treat breast, ovarian, endometrial, and uterine cancers.

- The most expensive oral anticancer medications prescribed to Californians are Revlimid (for multiple myeloma and myelodysplastic syndromes), Sutent (for gastrointestinal stromal tumors and for kidney, renal cell, and thyroid cancers), and Nexavar (for hepatocellular, kidney, renal cell, and thyroid cancers).

- The three oral anticancer medications that account for the largest share of total costs for such medications in California are Arimidex, Gleevec (for several types of leukemia, as well as dermatofibrosarcoma protuberans, desmoid tumors, gastrointestinal stromal tumors, myelodysplastic/myeloproliferative diseases, and systemic mastocytosis), and Xeloda (for brain tumors, islet cell tumors, and for breast, colon, esophageal, gastric, ovarian, pancreatic, and rectal cancers).

Utilization, Cost, and Coverage Impacts

Analysis approach: CHBRP modeled the impact of the mandate as a shift in cost sharing provisions. To perform the analysis, CHBRP compared current cost sharing (as a percentage of the cost of the medication) for oral cancer medications to current cost sharing for injectable/intravenous cancer medications. CHBRP then assumed that postmandate compliance with the mandate would result in the lower of the two cost sharing percentages being applied to oral cancer medications.

Table 1 summarizes the estimated utilization, cost and coverage impacts of SB 161.

Coverage

- Premandate, CHBRP estimates that the almost all enrollees with coverage subject to the mandate have at least some coverage for anticancer medications.
    - 100% of enrollees are estimated to have at least some coverage for inpatient anticancer medications and outpatient intravenous and injected anticancer medications.
    - 97.8% of enrollees are estimated to have at least some coverage for outpatient oral anticancer medications.
    - Approximately 472,000 enrollees (2.2%) have no coverage for outpatient oral anticancer medication.[1] This group includes persons with coverage from small group or individual market policies regulated by CDI.

Utilization

- CHBRP estimates that 0.4% of people with coverage subject to the mandate will use oral anticancer medications during the year following implementation.
- Of the people using outpatient anticancer medications, CHBRP estimates that 69.5% use oral only, 20.2% use injected or intravenous only, and 10.3% use a combination of oral and injected/intravenous anticancer medications.
- CHBRP estimates no measurable increase in the number of oral anticancer mediation users and no increase in the number of prescriptions per user because:
    - Premandate, 97.8% of enrollees with coverage subject to this mandate have some coverage for oral anticancer medications. In addition, public/private assistance programs exist to help with access to anticancer medications.
    - Price elasticity of demand[2] for anticancer medications is low. Cancer is a life-threatening illness, and patients will do whatever they can to comply with prescribed treatments.

[1] Some portion of this population may have coverage for generic (but not brand name) oral anticancer medications, but CHBRP is unable to specify. Therefore, the analysis assumes that none have coverage for any oral anticancer medications.

[2] Price elasticity of demand shows how the quantity demanded or supplied will change when the price changes.

- Oncologists' prescribing decisions seem unlikely to change materially, as there is little evidence that oncologists base their decisions on patient cost sharing requirements and because there are no intravenous or injected substitutes for many oral anticancer medications (and vice versa).

Costs

- The major impact of the bill would be to shift some oral anticancer medication costs from patients to health plans and policies. On average, the amount of the shift is estimated to be $98 per user per year.

    - Prior to the mandate, enrollees without coverage for oral anticancer medications (2.2% of enrollees with coverage subject to the mandate) are estimated to incur $8,440,000 in out-of-pocket expenses for such drugs in 2009. If the mandate were enacted, that $8,440,000 in out-of-pocket expenses would be shifted to health plans and policies. In addition, enrollees would see a further reduction of $6,227,000 due to lesser patient cost sharing requirements.

    - Approximately 1.6% of the enrollees among this population who use oral anticancer medications have out-of-pocket costs for such medications over $1,000 per year.

    - Postmandate amounts shifted from patient to plan/insurer would range from $0 to $7,800 per user per year. The wide variations is related to the price of particular oral anticancer medications and the cost sharing provisions of any one person's contract or policy.

- Total net annual expenditures are estimated to increase by $5,007,000 annually, or 0.0059%, mainly due to the administrative costs associated with the implementation of SB 161.

- The mandate is estimated to increase premiums by about $19,674,000. The distribution of the impact on premiums is as follows:

    - Total premiums for private employers are estimated to increase by $7,287,000, or 0.0144%.

    - Total employer premiums for California Public Employees' Retirement System (CalPERS) health maintenance organizations (HMOs) are estimated to increase by $282,000, or 0.0089%. Of the amount CalPERS would pay in additional total premiums, about 59%, or $166,000, would be the cost borne by the General Fund for CalPERS members who are state employees.

    - Enrollee contributions toward premiums for group insurance are estimated to increase by $1,704,000, or 0.013%.

    - Total premiums for those with individually purchased insurance are estimated to increase by $10,401,000, or 0.175%.

- In terms of per member per month (PMPM) costs, employer premiums for large groups are expected to increase by $0.0259 for DMHC-regulated plans and $0.0409 for CDI-regulated policies. Employer premiums for small groups are expected to increase by $0.0278 PMPM for DMHC-regulated plans and by $0.2401 PMPM for CDI-regulated policies.

- Although SB 161 would apply to Medi-Cal Managed Care plans and the Healthy Families program, these programs would not be expected to face any expenditure or premium increases because they currently provide oral anticancer medication benefits in accordance with the coverage mandated by the bill.

- Premiums are expected to increase by 0.025%. Increases in insurance premiums vary by market segment, ranging from approximately 0.01% to 0.470%. Increases as measured by PMPM payments are estimated to range from approximately $0.03 to $0.80. The greatest impact on premiums will be in the small group and individual markets regulated by CDI.

Public Health Impacts

- When compared to intravenous and injectable anticancer medications, oral anticancer medications have both advantages and disadvantages. Advantages include the facts that oral anticancer medications may allow administration of the medication on a daily basis, may be more convenient for patients, and may reduce the risk of infection or other infiltration complications. Disadvantages include less certainty in patient adherence to treatment regimens and a reduction in interaction between patients and their health care providers to manage complications of treatment.

- Utilization of oral anticancer medications is not expected to increase as a result of SB 161. Therefore, the only potential public health impact as a result of SB 161 is a reduction in out-of-pocket costs for oral anticancer medications. This could reduce the financial burden and related health consequences faced by cancer patients.

- Breast cancer is the most prevalent cancer in California, almost exclusively affecting women. Sixty-five percent of the prescriptions and 33% of the total cost for oral anticancer medications are for drugs used to treat breast cancer. Therefore, to the extent that SB 161 reduces out-of-pocket costs for patients, there is a potential to reduce the financial burden faced by women undergoing treatment for breast cancer.

- After breast cancer, the next three most common cancers in California are colorectal, prostate, and lung cancer. Non-Hispanic blacks in California have higher rates of diagnoses of these three cancers compared to all other racial and ethnic groups. These three cancers are all treated using oral anticancer medications; therefore, to the extent that SB 161 reduces out-of-pocket costs for oral anticancer medications, non-Hispanic black cancer patients could face a reduced financial burden.

- The utilization of oral anticancer medications is not expected to change as a result of SB 161. Therefore, there is no expected reduction in premature death or economic loss as a result of the passage of this mandate.

Table 1. Summary of Coverage, Utilization, and Cost Impacts of SB 161

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Coverage				
Total population in plans subject to state regulation (a)	21,340,000	21,340,000	0	0.000%
Total population in plans subject to SB 161	21,340,000	21,340,000	0	0.000%
Enrollees with coverage for oral anticancer medications				
Percentage	97.8%	100.0%	2.2%	2.261%
Number	20,868,000	21,340,000	472,000	2.261%
Enrollees with coverage for intravenous and injected anticancer medications				
Percentage	100%	100%	0	0.000%
Number	21,340,000	21,340,000	0	0.000%
Utilization and Cost				
Outpatient oral anticancer medication users per 1,000 member per year	85	85	0	0.000%
Oral anticancer medication prescriptions per 1,000 members with coverage per year	25.62	25.62	0	0.000%
Cost of oral anticancer medications				
Cost to health plans/insurers	$364,582,000	$379,249,000	$14,667,000	
Cost to enrollee cancer patients	$17,206,000	$2,539,000	−$14,667,000	
Expenditures				
Premium expenditures by private employers for group insurance	$50,546,207,000	$50,553,494,000	$7,287,000	0.0144%
Premium expenditures for individually purchased insurance	$5,944,229,000	$5,954,630,000	$10,401,000	0.1750%
Premium expenditures by individuals with group insurance, CalPERS, Healthy Families, AIM, or MRMIP (b)	$13,475,994,000	$13,477,698,000	$1,704,000	0.0126%
CalPERS employer expenditures (c)	$3,161,160,000	$3,161,442,000	$282,000	0.0089%
Medi-Cal state expenditures	$4,112,865,000	$4,112,865,000	$0	0.0000%
Healthy Families state expenditures	$643,247,000	$643,247,000	$0	0.0000%
Individual out-of-pocket expenditures for covered benefits (deductibles, copayments, etc.)	$6,384,077,000	$6,377,850,000	−$6,227,000	−0.0975%
Out-of-pocket expenditures for noncovered benefits	$8,440,000	$0	−$8,440,000	-100.000%
Total annual expenditures	$84,276,219,000	$84,281,226,000	$5,007,000	0.0059%

Source: California Health Benefits Review Program, 2009.
Notes: (a) This population includes privately insured (group and individual) and publicly insured (e.g., CalPERS, Medi-Cal, Healthy Families, AIM, MRMIP) individuals enrolled in health insurance products regulated by DMHC or CDI. This population includes enrollees aged 0-64 years and enrollees 65 years or older covered by employment sponsored insurance. (b) Premium expenditures by individuals include employee contributions to employer-sponsored health insurance and member contributions to public insurance. (c) Of the CalPERS employer postmandate expenditures, about 59%, or $166,000, would be state expenditures for CalPERS members who are state employees.
Key: CalPERS=California Public Employees' Retirement System

ACKNOWLEDGEMENTS

Janet Coffman, MPP, PhD, and Wade Aubry, MD, all of the University of California, San Francisco, prepared the medical effectiveness analysis. Bruce Abbott, MLS, of the University of California, Davis, conducted the literature search. Sara McMenamin, MPH, PhD, Matthew Ingram, BA, and Helen Halpin, ScM, PhD, of the University of California, Berkeley, prepared the public health impact analysis. Ying-Ying Meng, DrPH, of the University of California, Los Angeles, prepared the cost impact analysis. Jay Ripps, FSA, MAAA, of Milliman, provided actuarial analysis. Debi L. Reissman, PharmD, of Rxperts, and Charles L. Bennett, MD, PhD, MPP, of Northwestern University, provided technical assistance with the literature review and expert input on the analytic approach. John Lewis, MPA, of CHBRP staff prepared the background section and synthesized the individual sections into a single report. Cherie Wilkerson provided editing services. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Kathleen Johnson, PharmD, MPH, PhD, of the University of Southern California School of Pharmacy, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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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The California Health Benefits Review Program is administered by the Division of Health Sciences and Services at the University of California Office of the President, John D. Stobo, M.D., Senior Vice President – Health Sciences and Services.