CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

EXECUTIVE SUMMARY
Analysis of Assembly Bill 2174: Coverage for Amino Acid–Based Elemental Formula

A Report to the 2007–2008 California Legislature
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California Health Benefits Review Program Analysis of
Assembly Bill 2174: Coverage for Amino Acid–Based Elemental Formulas

The California Legislature has asked 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) 2174. As introduced by Assemblymember John Laird on February 20, 2008, this bill would mandate coverage of "amino acid–based elemental formulas, regardless of the delivery method, for the diagnosis and treatment of eosinophilic disorders and short bowel syndrome when the prescribing physician has issued a written order stating that the amino acid–based formula is medically necessary." AB 2174 would add Section 1367.27 to the Health and Safety Code, and Section 10123.197 to the Insurance Code.

Amino acid–based elemental formulas are complete nutrition formulas designed for individuals who have a dysfunctional or shortened gastrointestinal tract and are unable to tolerate and absorb whole foods or formulas composed of whole proteins, fats, and/or carbohydrates.

Eosinophilic disorders and short bowel syndrome (SBS) compromise a person's ability to ingest food orally. Persons with eosinophilic disorders may require elemental formulas administered by a feeding tube (enteral nutrition) or taken orally. Two of the more common eosinophilic disorders are those associated with the gastrointestinal tract: eosinophilic esophagitis (EE) and eosinophilic gastroenteritis (EG).

Persons with SBS receive nutrition through three stages: parenteral nutrition (intravenous administration), enteral nutrition, and introduction of solid foods. The enteral nutrition method most often used for these conditions is a gastric feeding tube, or "G-tube."

Health plans and insurers cover amino acid–based elemental formulas when administered by a feeding tube. These formulas are not typically covered when taken orally. The intent of the bill is for coverage of amino acid–based elemental formulas taken orally (i.e., by mouth) from a bottle or cup to be treated the same as coverage for amino acid–based elemental formulas administered by a feeding tube.

There is one California law currently mandating insurance coverage for formula—this law requires health plans and insurers to cover formula and special food products that are part of a prescribed diet deemed to be necessary for the treatment of phenylketonuria (PKU).

Medical Effectiveness

The medical effectiveness analysis examined the effectiveness of elemental formula for diagnosis and treatment of the two disorders addressed in AB 2174 for which literature on the effectiveness of formula was available: EE and SBS. No literature on the effectiveness of amino acid-based elemental formula was found for any other eosinophilic disorder.

Eosinophilic Esophagitis

- EE is a disorder involving inflammation of the esophagus caused by the infiltration of eosinophils (a type of white blood cell that facilitates the immune response to allergens) in response to environmental and food allergens. It affects adults and children, and hallmark symptoms are dysphagia[1], food impaction, vomiting, abdominal pain, weight loss, and failure to thrive in children.

- Treatment options include medication and dietary modification. There are two types of dietary modification.
    - Amino acid–based elemental formula is a hypoallergenic formula that provides nutrients in a simplified form and is easily absorbed.
    - Elimination diet is a treatment whereby foods that cause symptoms are identified and eliminated stepwise from an individual's diet.
- Few studies on the use of elemental formula to treat EE have been published.
    - Only four nonrandomized studies of the use of elemental formula to treat EE were identified.
    - No journal articles were found that addressed other eosinophilic disorders.
    - No studies were found that compared elemental formula and alternative treatments for EE, such as topical and systemic corticosteroids[2].
    - No studies were found that addressed using an elemental diet to treat adults with EE (i.e., the only studies identified assessed children).
- The evidence reviewed suggests that elemental formula improves the following clinical symptoms and histology associated with the food allergic response of EE:
    - Resolution of symptoms such as diarrhea, vomiting, poor weight gain, food refusal, and abdominal pain; and
    - Improvement of esophageal histology, as defined by the number of eosinophils visible upon endoscopic biopsy of the esophagus.
- However, findings from studies that compare the use of elemental formula to an elimination diet are ambiguous.

Short Bowel Syndrome

- SBS is a condition of severe malabsorption due to congenital defects of the gut or surgery to treat acquired diseases. If malabsorption becomes severe, the affected person is unable to maintain hydration and/or nutrient balance and requires the use of supplemental parenteral nutrition.

[1] People with dysphagia have difficulty swallowing and may also experience pain while swallowing.
[2] Corticosteroids mimic the effects of cortisone and hydrocortisone — hormones your body produces naturally in your adrenal glands. Corticosteroids suppress inflammation and are front-line treatments for many conditions.

- A therapeutic aim when treating SBS in adults is to restore intestinal function by providing nutritional requirements while the bowel undergoes adaptation. For children with congenital SBS, a major therapeutic aim is to promote normal growth and development. Parenteral nutrition is not a desirable method for treating SBS for extended periods as it can result in complications.

- Amino acid–based elemental formula may shorten the duration of parenteral nutrition therapy and facilitate a transition to oral intake of food, because it can be easily absorbed by the intestinal tract.

- Due to the rarity of these diseases, few research studies have addressed the use of elemental formula to treat SBS. CHBRP identified only three uncontrolled studies of children that assessed this topic. Evidence from these three studies suggest that elemental formula is associated with the following outcomes:

    - Decrease in duration of parenteral nutrition and successful transition to oral feeding.
    - Decrease in co-morbidities associated with SBS, such as episodes of bacterial sepsis.
    - Decrease in hospitalizations.

Utilization, Cost, and Coverage Impacts

Coverage

- Currently, 100% of the privately and publicly insured population have coverage for amino acid–based elemental formula when administered via a feeding tube.

- Currently, about 36% of the privately and publicly insured population, an estimated 8 million persons, have coverage for amino acid–based elemental formula taken orally. Coverage varies by market segment:

    - In the privately insured market, coverage is available to about 27% of enrollees. Of those with private insurance, coverage is higher in health insurance products regulated by the California Department of Insurance (59%) compared to health plans regulated by the Department of Managed Health Care (21%).
    - Elemental formula taken orally is not a covered benefit for California Public Employees' Retirement System (CalPERS) enrollees.
    - Low-income California residents who are enrolled in Medi-Cal or eligible for California Children's Services have coverage for elemental formula regardless of whether it is administered via a feeding tube or ingested orally.

- Of the insured population who are covered by health insurance products subject to this mandate, approximately 31,000 are estimated to have either an eosinophilic disorder or SBS. About 4.0 per 10,000 (8,900) individuals are estimated to have eosinophilic disorders and approximately 1.0 per 1,000 (22,400) individuals are estimated to have SBS.

- CHBRP estimates that approximately 14 million persons who currently do not have coverage for formula taken orally and gain this coverage after passage of this mandate.

Utilization

- CHBRP estimates about 1% of those individuals with SBS have coverage for elemental formulas because they are dependent on a feeding tube for nutritional support. CHBRP estimates there are no individuals with SBS who would have the feeding tube removed to rely exclusively on oral ingestion for nutritional support. This is based on input from experts who suggest that the feeding tube would remain in place both to maintain coverage of the formula and because poor palatability lowered patient compliance requiring frequent enteral feeding for those on a strict amino acid-based formula diet..

- CHBRP estimates no change in the utilization rates postmandate for the elemental formula for persons with eosinophilic disorders for the following reasons:

    - Neither the research literature nor claims data provide sufficient information to predict the percentage of individuals who would rely on formula taken orally as their exclusive or partial nutritional support.
    - Expert clinical opinion suggests that enrollees are currently using formula consistent with medically necessary treatment.
    - Financial difficulties due to the cost of these formulas may slightly reduce the quantity of oral formula used for those without coverage currently, but this effect cannot be quantified due to lack of such data.
    - Any potential increase in utilization would be offset by issues such as the poor taste and unpalatability of these products leading to lower than desired compliance levels.
    - Baseline utilization levels are based on maximum use of formula per individual, due to lack of data on the current level of utilization.

- AB 2174 does not preclude carriers from charging copayments, coinsurance, deductible, or other cost sharing for this benefit. The bill also does not preclude carriers from conducting health plan utilization or medical necessity reviews for coverage of formula to be taken orally.

Costs

- CHBRP has estimated an average annual cost of $11,500 per patient for orally administered formula. This cost is based on maximum level of utilization for children and adults and a weighted average of the unit cost of such formulas.

- Total expenditures are estimated to increase by $1,701,000 (0.0021%) annually, solely due to the additional administrative costs associated with providing coverage for persons who do not currently have this benefit.

- Prior to the mandate, enrollees without coverage for orally administered formula incurred an estimated $10,492,000 in out-of-pocket expenses annually. After the passage of AB 2174 those $10,492,000 in expenditures would be shifted to premiums by health plans insurers.

However, enrollees would incur an additional $829,000 in copayments for the newly covered benefits.

- The mandate is estimated to increase premiums by about $11,364,000. This increase would be distributed as follows:
  - Total premiums for private employers are estimated to increase by $7,784,000, or 0.0165%. In the large-group market, this is an increase of 0.0181% ($0.0532 PMPM) in the DMHC-regulated market, and 0.0074% ($0.0296 PMPM) in the CDI-regulated market. In the small-group market this is an increase of 0.0147% ($0.0498 PMPM) in the DMHC-regulated market, and 0.0074% ($0.0265 PMPM) in the CDI-regulated market.
  - Total employer premium expenditures for CalPERS are estimated to increase by $562,000, or 0.0191% ($0.0676 PMPM).
  - Premiums paid by employees covered by group insurance (including CalPERS) would increase by an estimated $2,093,000 or 0.0163%.
  - Total premiums for those with individually purchased insurance are estimated to increase by $925,000, or 0.0150%. This is an increase of 0.0152% ($0.0448 PMPM) in the DMHC-regulated market, and 0.0144% ($0.0232 PMPM) in the CDI-regulated individual market.

Public Health Impacts

- Population-based prevalence estimates exist for EE; however, the rates vary according to the study, with one estimate of 4.3 per 10,000 children and another adult estimate of 2.3 per 10,000 adults.

- The prevalence of SBS, in particular, is hard to estimate due to the numerous rare conditions that can result in SBS. Prevalence estimates are based on data of persons using home parenteral nutrition and estimates are approximately 4 cases per million adults and 3 cases per million children.

- The health outcomes associated with use of amino acid–based elemental formula include decrease in symptoms (e.g., dysphagia, pain, vomiting) of eosinophilic disorders and SBS, a shorter duration of parenteral nutrition, and improved quality of life.

- AB 2174 would not result in an increase in utilization of amino acid elemental formula for eosinophilic disorders and SBS; however, it would increase insurance coverage for this benefit and thus decrease out-of-pocket expenditures for approximately 900 individuals. While these 900 individuals are not expected to incur any improved health outcomes due to AB 2174, this bill would likely reduce the administrative burden and financial hardship associated with these disorders.

- Although there are clearly some gender and racial differences for diseases and conditions related to AB 2174, the gender and racial breakdown for all persons who would be affected

by AB 2174 is unknown. Still, since AB 2174 is not anticipated to affect utilization of amino acid–based elemental formula, AB 2174 is not expected to have a measurable impact on gender, racial, or ethnic disparities in health.

- AB 2174 is not expected to result in a reduction in premature death or the economic costs associated with eosinophilic disorders and SBS.

Table 1. Summary of Coverage, Utilization, and Cost Impacts of AB 2174

	Before Mandate	After Mandate	Increase/ Decrease	Change After Mandate
Coverage				
Number of individuals subject to the mandate	22,362,000	22,362,000	0	0.0%
Percentage of individuals with coverage				
Formula used with a feeding tube	100.0%	100.0%	0.0%	0.0%
Formula used without a feeding tube	35.9%	100.0%	64.1%	178.9%
Number of individuals with coverage				
Formula used with a feeding tube	22,362,000	22,362,000	0	0.0%
Formula used without a feeding tube	8,019,300	22,362,000	14,342,700	178.9%
Utilization and cost				
Number of members using formula with a feeding tube				
As a covered benefit	100	100	0	0.0%
As a non-covered benefit	0	0	0	0.0%
Total	100	100	0	0.0%
Number of members using formula orally				
As a covered benefit	500	1400	900	178.9%
As a non-covered benefit	900	0	-900	-100.0%
Total	1,400	1,400	0	0.0%
Average annual formula cost per user	$11,500	$11,500	0	0%
Expenditures				
Premium expenditures by private employers for group insurance	$47,088,966,000	$47,096,750,000	$7,784,000	0.0165%
Premium expenditures for individually purchased insurance	$6,158,288,000	$6,159,213,000	$925,000	0.0150%
Premium expenditures by individuals with group insurance, CalPERS, Healthy Families, AIM or MRMIP	$12,819,308,000	$12,821,401,000	$2,093,000	0.0163%
CalPERS employer expenditures	$2,942,984,000	$2,943,546,000	$562,000	0.0191%
Medi-Cal state expenditures (a)	$4,044,192,000	$4,044,192,000	$0	0.0000%
Healthy Families state expenditures	$644,074,000	$644,074,000	$0	0.0000%
Individual out-of-pocket expenditures (deductibles, copayments,etc.)	$5,602,060,000	$5,602,889,000	$829,000	0.0148%
Out-of-pocket expenditures for non-covered services	$10,492,000	$0	-$10,492,000	-100%
Total annual expenditures	$79,310,364,000	$79,312,065,000	$1,701,000	0.0021%

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 expenditures, about 60% or $337,000 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.
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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