



CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

EXECUTIVE SUMMARY

Analysis of Assembly Bill 163:
Amino Acid–Based Elemental
Formulas

A Report to the 2009-2010 California Legislature
March 30, 2009



The California Health Benefits Review Program (CHBRP) responds to requests from the State Legislature to provide independent analyses of the medical, financial, and public health impacts of proposed health insurance benefit mandates and proposed repeals of health insurance benefit mandates. In 2002, CHBRP was established to implement the provisions of Assembly Bill 1996 (California Health and Safety Code, Section 127660, et seq.) and was reauthorized by Senate Bill 1704 in 2006 (Chapter 684, Statutes of 2006). The statute defines a health insurance benefit mandate as a requirement that a health insurer or managed care health plan (1) permit covered individuals to obtain health care treatment or services from a particular type of health care provider; (2) offer or provide coverage for the screening, diagnosis, or treatment of a particular disease or condition; or (3) offer or provide coverage of a particular type of health care treatment or service, or of medical equipment, medical supplies, or drugs used in connection with a health care treatment or service.

A small analytic staff in the University of California's Office of the President supports a task force of faculty from several campuses of the University of California, as well as Loma Linda University, the University of Southern California, and Stanford University, to complete each analysis within a 60-day period, usually before the Legislature begins formal consideration of a mandate bill. A certified, independent actuary helps estimate the financial impacts, and a strict conflict-of-interest policy ensures that the analyses are undertaken without financial or other interests that could bias the results. A National Advisory Council, drawn from experts from outside the state of California and designed to provide balanced representation among groups with an interest in health insurance benefit mandates, reviews draft studies to ensure their quality before they are transmitted to the Legislature. Each report summarizes scientific evidence relevant to the proposed mandate, or proposed mandate repeal, but does not make recommendations, deferring policy decision making to the Legislature. The State funds this work through a small annual assessment on health plans and insurers in California. All CHBRP reports and information about current requests from the California Legislature are available at the CHBRP Web site, www.chbrp.org.

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EXECUTIVE SUMMARY

California Health Benefits Review Program Analysis of Assembly Bill 163: 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) 163. As introduced by Assembly Member Emmerson on January 27, 2009, this bill would mandate coverage of “amino acid–based elemental formulas, regardless of the delivery method, for the diagnosis and treatment of eosinophilic gastrointestinal disorders when the prescribing physician has issued a written order stating that the amino acid–based formula is medically necessary.” AB 163 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 an immune response to allergens found in whole foods or formulas composed of whole proteins, fats, and/or carbohydrates.

Eosinophilic gastrointestinal disorders (EGID)—often associated with food allergies—produce inflammation in the gastrointestinal track that compromises a person’s ability to take food orally. Treatments for persons with EGID include restricted diets (diets that eliminate the food allergens), oral and inhaled steroids, esophageal dilation (a procedure that dilates, or stretches, a narrowed area of the esophagus), and amino acid–based elemental formulas.

In California, health plans and insurers provide coverage of amino acid–based elemental formulas when administered by a feeding tube (enteral nutrition). Coverage is less common when the formulas are ingested orally. The intent of the bill is for coverage of amino acid–based elemental formulas to be treated the same regardless of the method of administration (e.g., oral, tube feedings).

Medical Effectiveness

The medical effectiveness analysis examined the effectiveness of elemental formula for the diagnosis and treatment of persons with EGID as addressed in AB 163. Literature on the effectiveness of amino acid–based elemental formula was found for only two eosinophilic disorders—eosinophilic esophagitis and eosinophilic gastroenteritis.

Eosinophilic Esophagitis (EE)

- 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 dysphagia¹, food impaction, vomiting, abdominal pain, weight loss, and inadequate weight gain in children.

¹ People with dysphagia have difficulty swallowing and may also experience pain while swallowing.

- Treatment options include medication and dietary modification. There are two types of dietary modification that may be provided exclusively or in combination with one another.
 - 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 from an individual’s diet.
- No randomized controlled trials (RCTs) have been conducted to assess the efficacy of elemental formula for the treatment of EGID.
- Four nonrandomized studies on the use of elemental formula to treat EE have been published. Two of these studies were case series involving small numbers of subjects that did not include a comparison group.
 - No studies were found that addressed using an elemental diet to treat adults with EE.
 - The evidence reviewed suggests that elemental formula improves the following clinical symptoms and histology associated with the food allergic response of EE:
 - Symptoms such as diarrhea, vomiting, poor weight gain, food refusal, and abdominal pain; and
 - Esophageal histology, as defined by the number of eosinophils visible upon endoscopic biopsy of the esophagus.
- However, results of studies that compare the use of elemental formula to an elimination diet are ambiguous.
- Studies are currently underway to investigate the potential of therapeutics targeting interleukin-5 (IL-5) as a treatment for patients with EE. Phase I/II clinical trials have demonstrated promising results, but results of phase III trials are not yet available and no anti-IL-5 medications have been approved for marketing in the United States. The impact of these medications on future use of elemental formula to treat EE is unknown.

Eosinophilic Gastroenteritis (EG)

- EG is a rare condition involving eosinophilic infiltration in one or more areas of the gastrointestinal tract.
- The evidence regarding the effectiveness of elemental formula as a treatment for EG is very limited. A case study of one child found that symptoms of EG improved after 9 weeks of dietary therapy with elemental formula. However, findings from this single case may not generalize to other persons with EG.

Utilization, Cost, and Coverage Impacts

Coverage

- Currently, 99% of the privately and publicly insured population subject to state regulation has coverage for amino acid–based elemental formula when administered via a feeding tube.

- Currently, about 35% of this population (an estimated 7.5 million persons) has coverage for amino acid–based elemental formula taken orally. Coverage varies by market segment:
 - In the privately insured market, coverage is available to about 25% of enrollees. Of those with private insurance, coverage is higher in health insurance products regulated by the California Department of Insurance (CDI) (55%) compared to health plans regulated by the Department of Managed Health Care (DMHC) (20%).
 - 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 are 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 covered by health insurance products subject to this mandate, approximately 4 per 10,000 individuals—for a total of 8,500—are estimated to have EGID.
- CHBRP estimates that approximately 13.8 million persons who currently do not have coverage for formula taken orally or via feeding tube would gain this coverage after passage of this mandate. Thus, of the 8,500 people with EGID, approximately 615 persons who currently do not have coverage for formula that they take via tube (3 people) or orally (612) would gain this coverage after passage of this bill.

Utilization

- CHBRP estimates no change in the utilization rates post-mandate for the use of elemental formula among persons with EGID for the following reasons:
 - Expert clinical opinion suggests that enrollees are currently using formula—either orally or via tube—consistent with medically necessary treatment.
 - Experts also suggest that anyone receiving formula via feeding tube would keep such a tube in place, even if oral formula were to be covered. The reason for this is that enteral feeding is most often required for those on a strict amino acid–based formula diet because of poor patient compliance with oral formula due to its unpalatability. CHBRP therefore assumes that there would be no shift in formula ingestion route; e.g., those taking it via tube would continue to do so, and those consuming it orally would likewise continue, and in the same quantities.
 - While financial difficulties resulting from the cost of these formulas may slightly reduce the quantity of oral formula used for those without current coverage, decreased demand because of limitations in insurance coverage cannot be quantified due to lack of data; expert opinion indicates any such effect would be negligible.
 - Any potential increase in utilization that may otherwise occur with increased insurance coverage would be offset by issues such as the unpalatability of these products, leading to lower than desired compliance levels.

- Baseline utilization levels are based on the upper bound estimates of formula use per individual because claims data or published research are not available on exact utilization levels.
- AB 163 does not preclude carriers from charging copayments, coinsurance, deductible, or other cost sharing for this benefit as is done for most currently covered services. 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 \$13,900 per patient for orally administered formula. This cost is calculated using a weighted average utilization for children and adults based on recommended daily doses for each group, and average unit costs of such formulas.
- Total expenditures are estimated to increase by \$1,378,000 (0.0016%) annually, solely due to the additional administrative costs associated with providing coverage for persons who do not currently have this benefit. Because administrative costs are assumed to be a fixed proportion of premiums, there is an increase in administrative costs solely due to the shift in costs from out-of-pocket expenditures to insurance premiums.
- Prior to the mandate, enrollees without coverage for elemental formula incurred an estimated \$8,543,000 in out-of-pocket expenses annually. After the passage of AB 163, those expenditures would be shifted to premiums by health plans insurers. However, enrollees would incur an additional \$722,000 in copayments for the newly covered benefits as a result of the increased administrative costs of providing orally administered formula as a mandated benefit. Thus, all except for \$722,000 of the pre-mandate \$8.5 million in out-of-pocket costs would be shifted from enrollees to insurers post-mandate.
- The mandate is estimated to increase premiums by about \$9,199,000. This increase would be distributed as follows:
 - Total premiums for private employers are estimated to increase by \$6,312,000, or 0.0125%. In the large-group market, this is an increase of 0.0130% (\$0.0453 PMPM) in the DMHC-regulated market, and 0.0065% (\$0.0284 PMPM) in the CDI-regulated market. In the small-group market this is an increase of 0.0137% (\$0.0437 PMPM) in the DMHC-regulated market, and 0.0067% (\$0.0230 PMPM) in the CDI-regulated market.
 - Total employer premium expenditures for CalPERS are estimated to increase by \$478,000, or 0.0151% (\$0.0572 PMPM).
 - Premiums paid by employees covered by group insurance (including CalPERS) would increase by an estimated \$1,693,000 or 0.0126%.
 - Total premiums for those with individually purchased insurance are estimated to increase by \$716,000, or 0.0120%. This is an increase of 0.0122% (\$0.0402 PMPM) in the DMHC-regulated market, and 0.0118% (\$0.0200 PMPM) in the CDI-regulated individual market.

Public Health Impacts

- The primary health outcome associated with use of amino acid–based elemental formula is a decrease in symptoms (e.g., dysphagia, pain, vomiting) related to EGID.
- AB 163 would not result in an increase in utilization of amino acid–based elemental formula for EGID; however, it would increase insurance coverage for this benefit and thus decrease out-of-pocket expenditures for 615 individuals. While these individuals are not expected to incur any improved health outcomes due to AB 163, this bill would reduce the financial hardship associated with these disorders.
- Males are more likely than females to be diagnosed with EE. Racial and ethnic differences in prevalence of EGID and utilization of amino acid–based elemental formula are unknown. AB 163 is not expected to have measurable impact on gender, racial, or ethnic disparities in health.
- AB 163 is not expected to result in a reduction in premature death or the economic costs associated with EGID.

Table 1. Summary of Coverage, Utilization, and Cost Impacts of AB 163

	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	0.0%
Total population in plans subject to AB 163	21,340,000	21,340,000	0	0.0%
Percentage of individuals with coverage				
Formula used with a feeding tube	99%	100%	1%	0.8%
Formula used without a feeding tube	35%	100%	65%	182.5%
Number of individuals with coverage				
Formula used with a feeding tube	21,161,800	21,340,000	178,200	0.8%
Formula used without a feeding tube	7,553,800	21,340,000	13,786,200	182.5%
Utilization and Cost				
Number of members using formula with a feeding tube				
As a covered benefit	300	303	3	0.8%
As a noncovered benefit	3	0	-3	-100%
Total	303	303	0	0.0%
Number of members using formula orally				
As a covered benefit	335	947	612	183%
As a noncovered benefit	612	0	-612	-100%
Total	947	947	0	0.0%
Average annual formula cost per user	\$13,900	\$13,900	\$0	0.0%
Expenditures				
Premium expenditures by private employers for group insurance	\$50,546,207,000	\$50,552,519,000	\$6,312,000	0.0125%
Premium expenditures for individually purchased insurance	\$5,944,229,000	\$5,944,945,000	\$716,000	0.0120%
Premium expenditures by individuals with group insurance, CalPERS, Healthy Families, AIM, or MRMIP (b)	\$13,475,994,000	\$13,477,687,000	\$1,693,000	0.0126%
CalPERS employer expenditures (c)	\$3,161,160,000	\$3,161,638,000	\$478,000	0.0151%
Medi-Cal state expenditures (d)	\$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	\$6,384,799,000	\$722,000	0.0113%
Out-of-pocket expenditures for non-covered benefits	\$8,543,000	\$0	-\$8,543,000	-100%
Total Annual Expenditures	\$84,276,322,000	\$84,277,700,000	\$1,378,000	0.0016%

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. Population includes enrollees aged 0 to 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 \$478,000 in added CalPERS employer expenditures, about 59% or \$282,020 would be state expenditures for CalPERS members who are state employees; (d) Medi-Cal state expenditures for members under 65 years of age include expenditures for 7,000 newly covered by the Major Risk Medical Insurance Program (MRMIP) and 7,000 newly covered in the 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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California Health Benefits Review Program Committees and Staff

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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