CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

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

A Report to the 2007-2008 California Legislature
April 8, 2008

CHBRP 08-06

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.

A Report to the 2007-2008 California State Legislature

Analysis of Assembly Bill 2174
Coverage for Amino Acid–Based Elemental Formulas

April 8, 2008

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PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 2174, a bill to mandate the coverage of amino acid–based elemental formulas for the diagnosis and treatment of eosinophilic disorders and short bowel syndrome. In response to a request from the California Assembly Committee on Health on February 8, 2008, the California Health Benefits Review Program (CHBRP) undertook this analysis pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as chaptered in Section 127600, et seq. of the California Health and Safety Code.

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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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EXECUTIVE SUMMARY

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.

INTRODUCTION

Assembly Bill (AB) 2174, introduced by Assemblymember John Laird, 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."

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. The enteral nutrition method most often used for these conditions is a gastric feeding tube, or "G-tube." Health plans and insurers typically do not cover these formulas when taken orally (i.e. by mouth) from a bottle or cup. The intent of the bill is for coverage of amino acid–based elemental formulas taken orally to be treated the same as coverage for amino acid–based elemental formulas administered enterally.

The California Health Benefits Review program (CHBRP) undertook an analysis of AB 2174 in response to a request from the California Assembly Committee on Health on February 8, 2008, pursuant to the provisions of Senate Bill 1704 (Chapter 684, Statutes of 2006) as chaptered in Section 127600, et seq. of the California Health and Safety Code. 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

Amino acid–based elemental formulas are one form of treatment for both eosinophilic disorders and SBS from various causes. Persons with eosinophilic disorders and SBS are unable to digest most foods without suffering complications. Elemental formulas are complete nutritional 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. Whole foods are home-prepared and significantly unaltered foods, such as blenderized or pureed table foods. Amino acid–based elemental formulas are made from individual (single) non-allergenic amino acids unlike regular dairy (milk or soy based) formulas and foods that contain many complete proteins. Amino acid–based elemental formulas are made

of proteins broken down to their “elemental level” so that they can be easily absorbed and digested.

Populations Affected by AB 2174

The population relevant to AB 2174 are persons with eosinophilic disorders and SBS who use amino acid–based elemental formulas. Two of the more common eosinophilic disorders are those associated with the gastrointestinal tract: eosinophilic esophagitis (EE) and eosinophilic gastroenteritis (EG).

Eosinophilic Disorders

Eosinophilic disorders, including EE and EG, are caused by eosinophils (a type of white blood cell) at abnormal levels in the tissues and blood stream. Eosinophils occur in small numbers naturally in everybody and they help fight infections caused by parasites and play a role in allergic responses. When eosinophils are present in abnormally high levels, inflammation and tissue damage can occur.

Due to the rarity of these conditions, few population-based prevalence estimates are available. No literature was identified that estimated the prevalence of EG. Studies of EE report that the condition is more frequently identified in children. One study found a prevalence of 4.3 per 10,000 children aged 0-19 years (Noel et al., 2004). A study of adults in Switzerland estimated the annual incidence to be approximately 1.4 cases per 100,000 adults and a prevalence of 2.3 per 10,000 adults (Straumann and Simon, 2005). The previous studies identified patients with EE at medical facilities when patients were seeking treatment. In contrast, Ronkainen et al. (2007) describes a study in Sweden where researchers performed upper gastrointestinal endoscopies on a random sample of the adult population and found substantially higher prevalence of EE with 4 in 1,000 having definite EE and 11 in 1,000 having definite or probable EE.

A substantial increase in EE prevalence has been found in recent years. Noel et al. (2004) found a four-fold increase from 2000 to 2004. Some researchers attribute the increase in prevalence to a real increase in disease while others attribute it to an increase in recognition of the disease (Straumann and Simon, 2005; Vanderheyden et al., 2007).

Short Bowel Syndrome

Persons with SBS have difficulties absorbing and digesting food. SBS in infants and small children usually results from congenital intestinal anomalies or necrotizing enterocolitis. SBS in adults usually results from surgery.

Prevalence of SBS is hard to estimate due to the numerous rare conditions that can result in SBS including Crohn’s disease, mesenteric infarction, radiation enteritis, intestinal volvulus, necrotizing enterocolitis, intestinal atresias, gastroschisis, Hirschsprung’s disease, and several other rare conditions (Koffeman et al., 2003). Prevalence estimates are based on data of persons using home parenteral (intravenous) nutrition and estimates are approximately 4 cases per million adults and 3 cases per million children. However, these figures likely underestimate SBS prevalence due to the reliance on home parenteral nutrition for population-based estimates (Koffeman et al., 2003).

Current Law

Health plans regulated by the California Department of Managed Health Care (DMHC) are required to provide a minimum basic set of health care services, as medically necessary. Health insurance products regulated by the California Department of Insurance (CDI) have no statutory minimum services, except specific mandated benefits. There is one California law currently mandating insurance coverage for formula—it 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).[3]

State Activities

Persons with these conditions who do not have coverage through their private insurance or Medi-Cal may qualify for one of two government-sponsored programs serving the low-income and uninsured: Women, Infants, and Children (WIC) and California Children's Services (CCS).

WIC Program[4]

WIC serves low-income pregnant, postpartum, and breastfeeding women, and infants and children up to age 5. Special therapeutic infant formulas may be provided when prescribed by a physician for a specified medical condition. Beneficiaries must meet income guidelines, a State residency requirement, and be individually determined to be at "nutrition risk" by a health professional. Two major types of nutrition risk are recognized for WIC eligibility:

- Medically based risks such as anemia, underweight, overweight, history of pregnancy complications, or poor pregnancy outcomes.
- Dietary risks, such as failure to meet the dietary guidelines or inappropriate nutrition practices.

To be eligible on the basis of income, applicants' income must fall at or below 185% of the U.S. Poverty Income Guidelines (currently $35,798 for a family of four).

California Children's Services

In general, CCS covers medical conditions that are physically disabling or require medical, surgical or rehabilitative services. For medical conditions requiring nutrition support in order to prevent or treat malnutrition, enteral nutrition products are a covered benefit.[5]

The program services persons who:

- are under 21 years old;
- have a medical condition that is covered by CCS;
- are residents of California; and

[3] Health and Safety Code Section 1374.56 and Insurance Code Section 10123.89
[4] USDA, WIC Fact Sheet, March 2008.
[5] "Enteral" commonly refers to a substance given via the digestive tract. CCS Numbered Letter 22.0805 dated 8-12-2005, Subject: Enteral Nutrition Products as a CCS Benefit.

- have a family income of less than $40,000, or out-of-pocket medical expenses for a child who qualifies that are expected to be more than 20% of family income[6], or a child with Healthy Families coverage.

Legislative Activities in Other States and Nationally

Eight states have legislative mandates for amino acid–based formula for one or more of the following diseases and conditions: severe food allergies, food protein intolerance, short bowel syndrome, and eosinophilic disorders. These states are Arizona, Connecticut, Illinois, Massachusetts, Minnesota, New Hampshire, New Jersey, and New York.[7]

At the federal level, there are no bills specific to coverage for elemental formulas. One bill, HR. 2719 (Rep. Burton, IN), amends the Internal Revenue Code to treat amounts paid for foods for special dietary use, dietary supplements, and medical foods as medical expenses for purposes of the medical expense tax deduction.

[6] Based on data from the U.S. Census Bureau that has been adjusted for inflation, the median household income in California in 2005 was $54,385. Given the estimated average annual cost for treatment for elemental formula ($11,500), the average annual cost of medical treatment services would be about 21% of median household income.
[7] American Partnership for Eosinophilic Disorders, www.apfed.org.

MEDICAL EFFECTIVENESS

AB 2174 would require health care plans and insurance carriers to provide coverage for amino acid–based elemental formula for the diagnosis and treatment of eosinophilic disorders and SBS. These disorders compromise a person's ability to ingest food orally, and existing treatment options such as parenteral nutrition (for SBS) and medication (for EE) are not optimal therapy in many cases. Amino acid–based elemental formula has been investigated as a treatment option to address these disorders, because simplification of nutrient components and the hypoallergenicity of elemental formula facilitate absorption of nutrients. Because literature on the effectiveness of amino acid-based elemental formula for eosinophilic disorders was found for EE only, this section of the report describes the disease pathology and clinical symptoms associated with EE and SBS, and summarizes the evidence of the therapeutic effects of using amino acid–based elemental formula to treat these conditions.

Literature Review Methods

The scope of the medical effectiveness literature reviewed for this report included pertinent studies published in English from 1997 to 2007. Specifications were as follows: study populations include both males and females, persons of all ages, and all types of study designs were satisfactory, as long as they addressed the clinical question of the treatment efficacy of elemental formula and eosinophilic disorders and SBS. The literature review identified seven pertinent studies. The medical effectiveness team obtained background information from seven additional articles. Further details about the literature review are presented in *Appendix B.*

The rarity of eosinophilic disorders and SBS in the general population affects the scope of the medical effectiveness literature on these topics. Few studies address the clinical question of amino acid–based elemental formula as effective treatment for these conditions. Research articles and literature retrieved were comprised primarily of case series, case reports, consensus/opinion statements, book chapters, narrative reviews, and of most significance, studies that involved comparison groups. However, these comparison studies were nonrandomized and uncontrolled.

There are no published randomized controlled trials (RCTs) on the effectiveness of amino acid–based elemental formula for eosinophilic disorders and SBS. No journal articles were found that addressed other eosinophilic disorders other than EE. Although EE affects both adults and children, no studies were found that examined amino acid–based elemental formula as nutritional therapy for adults. No studies were found that compared elemental formula and pharmaceutical treatments for EE, such as topical and systemic corticosteroids. No articles were found that assessed elemental formula as treatment for SBS in adults.

Findings

<u>Eosinophilic Esophagitis</u>

EE is a disorder involving inflammation of the esophagus caused by the infiltration of eosinophils (a type of white blood cell that controls the immune response to allergens) in

response to environmental and food allergens. The cause of EE is not fully understood. It may be an allergic disorder, an abnormal immunologic response, or a result of severe acid reflux disease. Experts believe that EE is governed by a coordinated allergic and immunologic response (Liacouras, 2006). Prior to 1995, EE was only understood as a case description; the etiology of the disease was not known. Kelly et al. (1995) concluded that there was a causal relationship between food allergy and EE. While the immunopathogenesis of EE also stems from an allergic response to environmental allergens and the pro-inflammatory cytokines IL-5 and IL-6, the rationale for prescribing amino acid–based elemental formula is based on the food allergic response of EE.

Diagnosis and clinical symptomology of eosinophilic esophagitis

Adults and children with EE vary in clinical presentation of symptoms. Children present usually with symptoms of chest pain, vomiting, abdominal pain, regurgitation of food, dysphagia, or food impaction. Severe symptoms can cause failure to thrive and weight loss among the affected children. Most adults, however, present with chronic and intermittent dysphagia, and repeat episodes of food impaction that often require endoscopy to resolve. Adults with EE are usually men in their 30s and 40s with a history of an allergic or atopic disposition. The differences in symptomology between adults and children are not well understood and it is yet unknown whether the pediatric form of EE progresses into the adult form of the disease (Pasha et al., 2006).

Currently, the diagnosis of EE is ascertained by endoscopy with biopsy. A count of 20 or more eosinophils per high-power field (HPF) in the esophagus confirms diagnosis, and less than 10 eosinophils/HPF indicates significant histological improvement of the condition (Pasha et al., 2006).

Treatment of eosinophilic esophagitis

Treatment of EE encompasses dietary therapy, medication management (in particular systemic and topical corticosteroids), and medical procedures such as esophageal dilation (performed with or without an endoscope). Treatment efficacy has not been well established, because rigorous studies have not been conducted to investigate the merits of current treatment options. Treatment recommendations are based mostly on clinical experience, expert consensus, and case series.

Amino acid–based elemental formula and eosinophilic esophagitis

The efficacy of amino acid–based elemental formula as treatment for EE is not certain, and elimination diets have also been advanced as a dietary strategy to treat the disease. The primary appeal of dietary management of the disease is that it is an alternative to pharmacologic treatment. The treatment rationale for using elemental formula as opposed to an elimination diet is that eliminating the allergic foods commonly associated with EE (e.g., milk protein, soy, egg, wheat, peanut/tree nuts, and seafood) often cannot alleviate symptoms. Elemental formula may be a more effective treatment for some persons because it is hypoallergenic. Either type of dietary therapy may cause nutritional deprivation, is a hardship for patients and families (especially if tube feeding is required in the case of elemental formula), and may lead to psychological difficulties and food aversion (Kagalwalla et al., 2006).

Summary of study findings

The studies reviewed looked at prognostic factors associated with relief and remission of EE. Resolution of the aforementioned clinical symptoms was a primary outcome in all the studies. Improvement of esophageal histology (as previously defined in this discussion) was also investigated by all the studies reviewed. The two studies that investigated only elemental formula as a treatment regimen for EE concluded that elemental formula resolved clinical symptoms and esophageal histology (Kelly et al., 1995; Markowitz et al., 2003). Kelly et al. found that upon follow-up biopsy after treatment with elemental formula, maximal intraepithelial eosinophils per HPF decreased significantly (pre-formula counts = median, 41 [range: 15-100]; post-formula counts = median, 0.5 [range: 0-22]), signifying improved histology. After receiving formula, 8 out of 10 patients resolved their symptoms and 2 out of 10 patients improved their symptoms. Markowitz et al. identified 51 children with EE and administered elemental formula to this cohort. Among these patients, there was significant improvement in the incidence of vomiting, abdominal pain, and dysphagia after treatment. The median number of esophageal eosinophils per HPF decreased from 33.7 before the diet to 1.0 after the diet. The average time to clinical improvement was 8.5 days.

Two studies compared elemental formula with elimination diet therapy. Both studies determined that elemental formula and food elimination diet were both effective at improving clinical symptoms and esophageal histology (Kagalwalla et al., 2006; Liacouras et al., 2005). It was not determined whether one regimen was superior to the other. Kagawalla et al. found that, after being treated with elemental formula, 88% of patients in this cohort achieved significant improvement in esophageal inflammation (less than 10 eosinophils/HPF), and 74% of those treated with elimination diet had also experienced such improvement. Liacouras et al. found that among those treated with elemental formula, pre-treatment values of histology were (average) 38.7 $\pm$ 10.3 esophageal eosinophils/HPF and post-treatment values were (average) 1.1 $\pm$ 0.6 esophageal eosinophils/HPF. The patients treated with elimination diet in this study also experienced improvement in histology; pre-treatment values of histology were (average) 47.5 $\pm$ 12.1 esophageal eosinophils/HPF and post-treatment values were (average) 5.3 $\pm$ 2.7 esophageal eosinophils/HPF.

Findings from the medical effectiveness literature review of EE suggest that amino acid–based elemental formula and elimination diet are both effective strategies to treat eosinophilic esophagitis. The evidence does not indicate which regimen is more effective.

Short Bowel Syndrome

SBS is a disorder that is typified by malabsorption and diarrhea due to a marked loss of small bowel length, either attributable to congenital defects or occurring after surgical intervention to treat acquired disease. Inadequate length of the intestinal tract prevents sufficient absorption of nutrients by enteral feeding. In adults, SBS is usually caused by surgical resection for Crohn's disease, malignancy, radiation, or vascular insufficiency. SBS in children and infants is often caused by congenital intestinal anomalies such as atresias, gastroschisis, or necrotizing enterocolitis. Severe malabsorption caused by SBS can become life-threatening when hydration and nutrient equilibrium can no longer be self-sustained. Management of SBS requires the use of supplemental parenteral nutrition (or total parenteral nutrition when used alone) to provide nutrients and to prevent fluid and electrolyte abnormalities (Vanderhoof and Young, 2008).

Amino acid–based elemental formula to treat short bowel syndrome

A therapeutic aim when treating SBS among infants and children is to restore intestinal function by providing nutritional requirements for normal growth and development while the bowel undergoes adaptation. Parenteral nutrition is not desired to treat SBS for extended periods, because prolonged dependence on parenteral nutrition is associated with the following complications: recurrent central venous catheter sepsis, cholestatic liver disease, end stage liver disease, cirrhosis, and inadequate bone mineralization. These morbidities are often related to the duration of parenteral nutrition therapy. Termination of parenteral nutrition support is important to achieve optimal outcomes. Transition to enteral feeding and oral intake of food is the primary treatment aim (Andorsky et al., 2001).

Amino acid–based elemental formula may shorten the duration of parenteral nutrition therapy and facilitate a transition to oral intake of food by improving diarrhea and vomiting, because elemental formula can be easily absorbed by the intestinal tract. Amino acid–based elemental formula is easier to absorb than formulas that contain complete proteins (i.e., cow's milk and soy formulas). The effectiveness of amino acid–based elemental formula to treat SBS in this capacity has been investigated by the three studies included in our medical effectiveness review.

Summary of study findings

All three studies assessed pediatric populations only. One study was a case report and thus evaluated just one infant. All study participants were on parenteral nutrition at the commencement of the trials. Duration of parenteral nutrition was the primary outcome assessed in all the studies. None of the studies included comparison groups.

All studies concluded that treatment with amino acid–based elemental formula was associated with shorter duration of parenteral nutrition. One study reported that co-morbidities associated with SBS improved upon treatment with elemental formula, such as episodes of bacterial sepsis (Bines et al., 1998). This study also found a reduction in the number of hospitalizations.

Findings from the medical effectiveness literature review of SBS suggest that amino acid–based elemental formula facilitates transition to oral feeding.

UTILIZATION, COST, AND COVERAGE IMPACTS

AB 2174 would require health plans regulated by the DMHC and health insurance products regulated by the CDI to provide coverage for amino acid–based elemental formulas taken orally for individuals with eosinophilic disorders and SBS, for enrollees in group (large and small) and individual markets. AB 2174 would not directly affect populations that are enrolled in health insurance products that are not subject to benefit mandates, such as those enrolled in self-insured plans or those who are uninsured.[8] There are no provisions in the bill that impact utilization or medical necessity reviews or the copayment, coinsurance, deductible, or other cost-sharing amounts set by health plans and insurers.

This section presents first the current, or baseline, costs and coverage related to coverage of, and then the estimated utilization, cost, and coverage impacts of AB 2174. For further details on the underlying data sources and methods, see *Appendix D.*

Present Baseline Cost and Coverage

Current Coverage of Mandated Benefit

Approximately 22,362,000 individuals in California are enrolled in health plans or policies that would be affected by this legislation. Currently all individuals with eosinophilic disorders and SBS are covered for the use of formula through a feeding tube.

CHBRP surveyed the major health plans and insurers regarding coverage. Responses to this survey represented 82.6% of the CDI-regulated and 93.9% of the DMHC-regulated market. Combined, responses to this survey represent 92.4% of the privately insured market. The results suggest that about 27% of the privately insured market have coverage for formula taken orally. The coverage of formula taken orally varies by market segment. Of those with private insurance, a greater proportion (59%) are covered by CDI-regulated health insurance products than covered by DMHC-regulated health plans (21%). Coverage for those in privately insured DMHC-regulated plans ranges from 18% in the large group, 28% in the small group, to 37% in the individual market. In the CDI-regulated market, coverage ranges from 53% in the large-group market, 55% in the small-group market, to 65% in the individual market.

In the publicly insured market segment, coverage varies from 0% for enrollees in CalPERS to 100% for enrollees in Medi-Cal and children in low-income households eligible for the CCS program.[9]

[8] SB 1704, CHBRP's authorizing legislation defines a benefit mandate bill as "a proposed statute that requires a health care service plan or a health insurer, or both, to …offer or provide coverage of a particular type of health care treatment or service" Thus, the portion of the population directly affected by a benefit mandate bill are those enrolled in a health insurance products offered by health care service plans or health insurers.

[9] CCS is designed to treat low-income persons with rare and complicated genetic and other disorders, and covers formula for these conditions for persons under age 21. CCS will cover all children with annual family incomes less than $40,000, or for whom the out-of-pocket expenses exceed 20% of their income. Based on these income criteria, a small number of privately insured individual may qualify for this program.

Combining those with private and public insurance, about 36% of the population affected by AB 2174, an estimated 8 million people, have coverage for amino acid–based elemental formula taken orally.

The prevalence of eosinophilic disorders and SBS is very low, estimated to be approximately 4 per 10,000 for eosinophilic disorders and 1 per 1,000 for SBS. These prevalence rates translate into approximately 8,900 persons with eosinophilic disorders and 22,400 persons with SBS who would be affected by the proposed mandate.[10]

Current Utilization Levels and Costs of the Mandated Benefit

Current utilization levels

The percentage of individuals with eosinophilic disorders who currently take formula orally is difficult to measure using claims data for a number of reasons, including: (1) diagnoses of eosinophilic disorders are rare; (2) formula taken orally is generally not reimbursed and therefore rarely appears in claims data; (3) where diagnostic claims data is available, it does not indicate the severity of the condition to assess whether the enrollee is receiving nutritional support orally or via a feeding tube; and (4) individuals with eosinophilic disorders may use the oral formula intermittently as their symptoms vary. The combination of these problems results in a lack of sufficient and reliable quantitative data on utilization. For example, CHBRP's review of the literature on prevalence of eosinophilic disorders seems to indicate a rate of 4 per 10,000 averaged over children and adults; however, only 9 individuals with these disorders were identified in claims data as being covered for formula via a feeding tube.

Because claims data was not reliable, CHBRP based its utilization estimates on a limited number of published studies. Based on these studies, CHBRP estimates the percentage of individuals with eosinophilic disorders who take formula orally to be 16% (Furuta, 2007). This percentage is a weighted average of use among infants, children aged 2-17, and adults. CHBRP assumes 100% of infants would use formula orally as their sole source of nutrition. For children aged 2-17, CHBRP estimates that 25% would use formula orally based on data reporting that approximately 75% of children with eosinophilic disorders respond to alternative treatment (i.e., an elimination diet). CHBRP estimates that the remaining 25% ingest amino acid–based elemental formula orally as it is identified as the gold standard for treatment of these conditions for those who do not respond to alternative treatments (Furuta, 2007). There are no published studies or claims data on adults' use of formula taken orally. Therefore, CHBRP has used a relatively conservative estimate of 10% for the adult population. This figure is based on the range of alternative treatments for adults, including elimination diets, medical management (including acid suppression, and systemic and topical corticosteroids), and medical procedures such as dilatation.

Identification of SBS in claims data is also difficult as coding of this condition can vary. SBS patients also vary in their need and use of formula: some will always depend on feeding through a feeding tube and an unknown percentage may transition to oral formula over time. The literature on prevalence of SBS and use of elemental formula either by oral or feeding-tube

[10] The prevalence rates for eosinophilic disorders were based on prevalence rates for EE, the only disorder for which there was information available.

administration is also sparse. It is likely that the great majority of those individuals would graduate to use of formulas, but the research literature is insufficient to determine the percentage that may graduate to oral formula. In the absence of any published data or evidence on prevalence of individuals with SBS who depend solely on orally administered formula, and based on input from a content expert, CHBRP assumes that those with feeding tubes would keep it in place for as long as the nutritional need for formula remains to take advantage of insurance coverage for the formula and because poor palatability of the formula lowers patient compliance requiring frequent enteral feeding for those on a strict amino acid-based formula diet. Based on claims data, CHBRP estimates the prevalence of SBS to be approximately 0.1%, with 0.6% using the feeding tube.

Unit price

CHBRP estimates an average annual cost of $11,500 per patient for the amino acid–based elemental formulas. In the absence of claims data on the level of use of these formulas, the unit price is calculated based on the retail price of the most common products used for these conditions, and the recommended daily dosages for individuals who use the formula as the only or the main source of nutrition for the whole year. Data on recommended dosages was supplied to CHBRP by clinical dieticians involved in the care of individuals with eosinophilic disorders and SBS. Formulas can be purchased through a pharmacy or by mail order and the price can vary as a result. The CHBRP estimated unit price is calculated as a weighted average of the nutritional needs of the various age groups and represents the upper bound of the amount of formula used. Population-based data on the length of time for use of formula or amount of use were not available to CHBRP. For some individuals with these conditions, formula would be a complementary source of nutrition.

The baseline costs associated with the mandate given current coverage levels, utilization, and unit price are presented in Table 2.

<u>The Extent to Which Costs Resulting from Lack of Coverage Are Shifted to Other Payers, Including Both Public and Private Entities</u>

Consumption of oral formula for some individuals is medically necessary and cannot be fully substituted with medication or food avoidance. Discussions with clinicians specializing in care of infants and young children with eosinophilic disorders indicate that some topical steroids may temporarily reduce the severity of the inflammation in the absence of formula, but it is not a replacement in most cases. Avoidance or elimination diets may also reduce the need for formula, but they are not sustainable as they may lead to nutritional deficiencies and failure to thrive in young children. In children with SBS who often have the operation to remove parts of the bowel shortly after birth, the use of formula through a feeding tube is the only alternative until they reach a stage when oral intake of food is possible. Most would remain dependent on these formulas for the long term to ensure adequate nutrition and health. Individuals with SBS also have a choice of keeping the feeding tube in place for as long as use of formula is needed to maximize insurance coverage. Thus, the medical necessity of use of formulas is established in most of the population subject to this mandate.

CHBRP estimates the potential increase in utilization due to the mandate would be minimal. Issues related to patient compliance, for example, would still exist since these products are

usually poor tasting and unpalatable. Consequently, AB 2174 would shift costs from out-of-pocket expenditures previously paid for by privately insured individuals to costs covered and paid for by health plans and insurers. No shifting of costs is estimated for those enrolled in public programs such as Medi-Cal and Healthy Families, since this benefit is covered by Medi-Cal and CCS for Healthy Families enrollees.

Public Demand for Coverage

To determine public demand for the proposed mandate (based on criteria specified under SB 1704 [2007]), CHBRP has examined the extent of collective bargaining and the self-insured plans coverage for the benefits specified under AB 2174. Currently, CalPERS preferred provider organization (PPO) plans are the largest public self-insured plans and they provide coverage similar to that of the privately self-insured plans. CalPERS PPO plans do not cover formulas except for formulas and special food products for treatment of phenylketonuria (PKU). CalPERS' PPO self-insured plans exclude vitamins, minerals, and nutritional supplements, whether available over the counter or prescribed by a physician, as a covered benefit. CalPERS PPO plans also exclude nutritional counseling or food supplements taken orally, except if they are covered under the diabetes self-management and education benefit or under the outpatient prescription drug benefit.

Based on conversations with the largest collective bargaining agents in California, CHBRP concludes that unions currently do not include coverage for elemental formulas in their health insurance policy negotiations. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and coinsurance levels.[11]

Impacts of Mandated Coverage

How Will Changes in Coverage Related to the Mandate Affect the Benefit of the Newly Covered Service and the Per-Unit Cost?

Impact on per-unit cost

Currently, formulas are generally prescribed for individuals for whom such treatment is medically necessary and, as described in the *Medical Effectiveness* section, use of formulas for individuals with SBS and eosinophilic disorders is generally effective. In addition, CHBRP assumes that the level of patient compliance/adherence in use of formulas would not be affected by AB 2174. Finally, eosinophilic disorder and SBS are rare and patient demand would not create price pressures postmandate. Since AB 2174 would not affect the effectiveness or the place price pressures on formulas, CHBRP does not anticipate any changes to the per-unit cost of these products due to AB 2174.

Postmandate coverage

AB 2174 would extend coverage to all privately and CalPERS-insured individuals for oral use of amino acid–based elemental formula; only 36% of this population is currently covered. Individuals with SBS have coverage for the use of formula through a feeding tube and are assumed to continue the use of feeding tube for as long as the formula is needed. Thus, CHBRP

[11] Personal communication with the California Labor Federation and member organizations on March 25, 2008.

does not estimate a change in their coverage due to the mandate. The same assumption holds for those with eosinophilic disorders who have a feeding tube. CHBRP estimates that about 1,400 individuals with eosinophilic disorders who use the formula orally would be covered due to the mandate.

Changes in coverage as a result of premium increases

CHBRP estimates premium increases of less than 1% in the privately insured market and CalPERS, discussed later in this section. CHBRP does not anticipate loss of insurance coverage, changes in availability of the benefit beyond those subject to the mandate, changes in offer rates of insurance, changes in employer contribution rates, changes in take-up of insurance by employees, or purchase of individual policies, due to the small size of the increase in premiums after the mandate. This premium increase would not have a measurable impact on number of individuals who are uninsured.

How Will Utilization Change as a Result of the Mandate?

The utilization of amino acid–based elemental formula taken administered by feeding tube or ingested orally is estimated to remain essentially unchanged under AB 2174. The utilization of formula among those with SBS or eosinophilic disorders who have a feeding tube would remain unchanged because there are no individuals with either condition 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 to maintain coverage by health plans and insurers and because poor palatability lowered patient compliance requiring frequent enteral feeding for those on a strict amino acid-based formula diet.

CHBRP also estimates no change in these utilization rates postmandate for the elemental formula for persons with eosinophilic disorders for several reasons. Based on expert clinical opinion, there is not an under-utilization of formula among those who ingest orally. Those with eosinophilic disorders who needed the oral formula for sufficient nutrition would have purchased it regardless of insurance coverage. For those with severe conditions, the medical necessity would outweigh cost concerns. It is likely that persons with less severe conditions who have delayed or limited purchase of formula and may increase utilization under AB 2174. In some cases, individuals needing formula may have attempted to use alternatives such as topical steroids and coverage under AB 2174 may reduce the number of physician office visits to relieve symptoms that could not be managed without the use of oral formula. Providers may have also delayed the performance of endoscopies for diagnosis of eosinophilic disorders if the use of oral formula alleviated the symptoms. However, CHBRP does not estimate a significant decrease in office visits or endoscopies or a significant increase in utilization of oral formula by these individuals. Lastly, 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.

Therefore, the potential increases in utilization levels are considered to be neglibible. CHBRP has estimated the baseline utilization of formula administered orally or through a feeding tube to be consistent with the amount necessary for nutritional support due to a lack of data on the exact level of use. Thus, the baseline estimates of utilization represent the upper bound levels for those who use formula for the treatment of their disorder.

To What Extent Does the Mandate Affect Administrative and Other Expenses?

All health plans and insurers include a component for administration and profit in their premiums. The estimated impact of AB 2174 on premiums includes the assumption that plans and insurers would apply their existing administration and profit loads to the marginal increase in health care costs produced by the mandate. Given that utilization rates would remain the same after the mandate, the estimated increase of total expenditures is mainly due to the increase of the administrative costs as a proportion of the premium. Under AB 2174, CHBRP estimates an increase of $1,701,000 in administrative costs for plans regulated by the DMHC and CDI.

Impact of the Mandate on Total Health Care Costs

Changes in total expenditures

Currently about $10,492,000 in out-of-pocket expenses is spent annually on the purchase of formula by enrollees without coverage. After the mandate, health plans and insurers would be required to cover this amount. Since this dynamic is a *cost shift* between types of expenditures— from out-of-pocket to premiums covered by insurance— total expenditures as a result of this shift would not change.

However, there is an administrative cost associated with expanding coverage for oral formula by health plans and insurers. Therefore, CHBRP estimates an increase in total expenditures of $1,701,000 (0.0021%) postmandate.

The breakdown of how the total increase in expenditures is distributed among premiums and cost sharing are summarized below.

- Employers' (including CalPERS) share of premium increases is estimated to be $7,784,000 (0.0165%).
- Enrollees in individually purchased plans would face an increases of $925,000 (0.0150%) in premiums.
- Enrollees' share of premium increases in the group plans is estimated to be $2,093,000 (0.0163%).
- CalPERS' enrollees share of premium increases is estimated to be $562,000 (0.0191%).
- Copayments, deductibles, and other forms of cost sharing by all insured is estimated to increase by $829,000 (0.0148%).

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CHBRP estimates no perceptible savings or offsets in other health care costs due to AB 2174 since the bill is not expected to significantly reduce or increase other types of health care services.

Costs or Savings for Each Category of Insurer Resulting from the Benefit Mandate

The shift in expenditures from out-of-pocket to health plans and insurers ranges in increases in premiums as follows:

- Large-group market: an estimated premium increase of 0.0181% ($0.0532 PMPM) in the DMHC-regulated market, and 0.0074% ($0.0296 PMPM) in the CDI-regulated market.

- Small-group market: an estimated premium increase of 0.0147% ($0.0498 PMPM) in the DMHC-regulated market, and 0.0074% ($0.0265 PMPM) in the CDI-regulated market.

- Individual market: an estimated premium increase of 0.0152% ($0.0448 PMPM) in the DMHC-regulated market, and 0.0144% ($0.0232 PMPM) in the CDI-regulated individual market.

- CalPERS: an estimated premium increase of 0.0191% ($0.0676 PMPM).

The projected cost impacts as a result of AB 2174 are summarized in Table 3.

Impact on Long-Term Costs

AB 2174 is not expected to have any noticeable long-term cost impacts. The mandate may reduce potential delays in treatment due to immediate coverage of formula. However, the effects of this change are unknown and are not estimated to change long-term expenditures.

Impact on Access and Health Service Availability

AB 2174 is estimated to impact access to orally administered amino acid–based formula by removing potential financial barriers when the formula is purchased without insurance coverage. The unit price of the formula is substantial enough to be a hardship for some individuals who need to receive it orally and are currently without such coverage. However, AB 2174 is not expected to improve the ease of purchasing or availability of such products, nor is it expected to impact the availability of these products.

Consumer complaints

Since 2001, the DMHC has received 48 complaints relating to special formulas and food products, including complaints related to over-the-counter supplements. The complaints covered a wide range of conditions, including PKU and Crohn's disease.[12] The percentage and nature of the complaints related to eosinophilic disorders or SBS are unknown.

Patients who dispute health plan denials because procedures are not considered medically necessary or are considered experimental or investigational can appeal to the California Independent Medical Review (IMR) Program. CHBRP searched DMHC's IMR database to identify patient disputes related to elemental formula for the conditions covered by AB 2174. Of the 6,000 appeals filed since 2000, CHBRP found no patient disputes regarding the medical necessity of elemental formulas. This is because benefits that are not included in the insured's coverage are not subject to medical necessity determinations.

[12] Personal communication with Sherrie Lowenstein, March 4, 2008.

Table 2. Baseline (Premandate) Per Member Per Month Premium and Expenditures by Insurance Plan Type, California, 2008

	Large Group		Small Group		Individual		CalPERS	Medi-Cal		Healthy Families	
	DMHC-Regulated	CDI-Regulated	DMHC-Regulated	CDI-Regulated	DMHC-Regulated	CDI-Regulated	HMO (a)	Managed Care 65 and Over	Managed Care Under 65	Managed Care	Total Annual
Population Currently Covered	11,721,000	342,000	3,256,000	728,000	1,299,000	812,000	815,000	172,000	2,532,000	685,000	22,362,000
Average Portion of Premium Paid by Employer	$238.92	$315.18	$245.82	$296.00	$0.00	$0.00	$300.92	$181.00	$120.01	$78.35	$54,695,911,000
Average Portion of Premium Paid by Employee	$54.60	$86.99	$93.75	$62.26	$294.46	$160.95	$53.10	$0.00	$0.80	$6.81	$19,001,902,000
Total Premium	$293.53	$402.17	$339.57	$358.26	$294.46	$160.95	$354.02	$181.00	$120.81	$85.17	$73,697,813,000
Member expenses for covered benefits (Deductibles, copays, etc.)	$15.78	$45.50	$24.95	$95.56	$50.61	$39.36	$18.26	$0.00	$0.56	$2.32	$5,602,060,000
Member expenses for benefits not covered	$0.05	$0.03	$0.04	$0.03	$0.04	$0.02	$0.06	$0.00	$0.00	$0.00	$10,492,000
Total Expenditures	$309.35	$447.70	$364.56	$453.85	$345.10	$200.33	$372.34	$181.00	$121.36	$87.49	$79,310,365,000

Source: California Health Benefits Review Program, 2008.
Note: The population includes individuals and dependents in California who have private insurance (group and individual) or public insurance (e.g., CalPERS, Medi-Cal, Healthy Families, AIM, MRMIP) under health plans or policies regulated by DMHC or CDI. All population figures include enrollees aged 0-64 years and enrollees 65 years or older covered by employment-based coverage.
Key: CalPERS = California Public Employees' Retirement System; HMO = health maintenance organization and point of service plans.

Table 3. Postmandate Impacts on Per Member Per Month and Total Expenditures by Insurance Plan Type, California, 2008

	Large Group		Small Group		Individual		CalPERS	Medi-Cal		Healthy Families	
	DMHC-Regulated	CDI-Regulated	DMHC-Regulated	CDI-Regulated	DMHC-Regulated	CDI-Regulated	HMO (a)	Managed Care 65 and Over	Managed Care Under 65	Managed Care	Total Annual
Population Covered	11,721,000	342,000	3,256,000	728,000	1,299,000	812,000	815,000	172,000	2,532,000	685,000	22,362,000
Average Portion of Premium Paid by Employer	$0.0433	$0.0232	$0.0361	$0.0219	$0.0000	$0.0000	$0.0575	$0.0000	$0.0000	$0.0000	$8,346,000
Average Portion of Premium Paid by Employee	$0.0099	$0.0064	$0.0137	$0.0046	$0.0448	$0.0232	$0.0101	$0.0000	$0.0000	$0.0000	$3,018,000
Total Premium	$0.0532	$0.0296	$0.0498	$0.0265	$0.0448	$0.0232	$0.0676	$0.0000	$0.0000	$0.0000	$11,364,000
Member expenses for covered benefits (Deductibles, copays, etc.)	$0.0029	$0.0033	$0.0037	$0.0071	$0.0076	$0.0057	$0.0035	$0.0000	$0.0000	$0.0000	$829,000
Member expenses for benefits not covered	-$0.0499	-$0.0285	-$0.0440	-$0.0276	-$0.0381	-$0.0212	-$0.0610	$0.0000	$0.0000	$0.0000	-$10,492,000
Total Expenditures	$0.0061	$0.0044	$0.0096	$0.0060	$0.0143	$0.0077	$0.0101	$0.0000	$0.0000	$0.0000	$1,701,000
Percentage Impact of Mandate											
Insured Premiums	0.0181%	0.0074%	0.0147%	0.0074%	0.0152%	0.0144%	0.0191%	0.0000%	0.0000%	0.0000%	0.0154%
Total Expenditures	0.0020%	0.0010%	0.0026%	0.0013%	0.0041%	0.0038%	0.0027%	0.0000%	0.0000%	0.0000%	0.0021%

Source: California Health Benefits Review Program, 2008.
Note: The population includes individuals and dependents in California who have private insurance (group and individual) or public insurance (e.g, CalPERS, Medi-Cal, Healthy Families, AIM, MRMIP) under health plans or policies regulated by DMHC or CDI. All population figures include enrollees aged 0-64 years and enrollees 65 years or older covered by employment-based coverage.
Key: CalPERS = California Public Employees' Retirement System; HMO = health maintenance organization and point of service plans.
(a) Of the CalPERS employer expenditures, about 60% or $337,000 would be state expenditures for CalPERS members who are state employees.

PUBLIC HEALTH IMPACTS

Impact of the Proposed Mandate on the Public's Health

The health outcomes associated with use of amino acid–based elemental formula include a decrease in symptoms (e.g., dysphagia, pain, vomiting) of eosinophilic disorders and SBS, a shorter duration of parenteral nutrition, and improved quality of life (Kukuruzovic et al., 2004).

According to the *Utilization, Cost, and Coverage Impacts* section, AB 2174 would not result in an increase in utilization of amino acid–based elemental formula for eosinophilic disorders and SBS. AB 2174 would, however, increase insurance coverage for this benefit and thus decrease out-of-pocket expenditures to 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.

The content experts for this analysis have suggested another potential benefit if AB 2174 were enacted into law. The benefit is primarily for infants and young children with SBS, who usually start taking the amino acid–based elemental formula via a gastric feeding tube and eventually try to transition to oral administration. Since insurance companies typically cover amino acid–based elemental formula if it is administered via a feeding tube, there is an economic incentive to remain on the feeding tube in order to maintain insurance coverage for the formula. If oral formula were an insured benefit, this economic incentive would be eliminated and could result in an earlier transition to oral formula, where children could learn oral self-feeding skills.

The Impact on the Health of the Community Where Gender and Racial Disparities Exist

A literature review was conducted to determine if gender and racial/ethnic disparities exist with regard to the prevalence, treatment, and health outcomes of eosinophilic disorders and SBS.

No gender differences were found between males and females for EG (Guajardo et al., 2002). For EE, however, males have a substantially higher prevalence compared to females with prevalence estimates ranging from twice as high to over five times as high among males (Assa'ad et al., 2007; Guajardo et al., 2002; Noel et al., 2004; Straumann and Simon, 2005; Vanderheyden et al., 2007).

While no literature was identified discussing gender differences in prevalence of SBS overall, there are some gender differences in the diseases and conditions that can sometimes lead to SBS. For example, Bernstein et al. (2006) found a higher incidence of Crohn's disease in females compared to males, and Nguyen et al. (2007) found that females with Crohn's disease were less likely to undergo a bowel resection.

The racial patterns for eosinophilic disorders and SBS also vary by condition. The few prevalence studies available on EE were conducted in predominately white populations and therefore do not present data by race (Ronkainen et al., 2007; Straumann and Simon, 2005). Overall, racial differences in SBS are unknown. However, some racial disparities exist in regard to the conditions related to SBS. Llanos et al. (2002) found statistically significantly higher incidence rates of necrotizing entercolitis (damage to the intestinal tissues) among black

newborns compared to whites. Holman et al. (1997) found an increased risk of necrotizing enterocolitis-associated death among black males. One study of Californian infants found that blacks had higher rates of gastrointestinal atresias (intestinal malformations) compared to other races (Harris et al., 1995). Another study found a significantly higher rate of jejunal atresias (intestinal malformations) among black infants compared to whites (Cragan et al., 1993).

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. 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.

The Extent to Which the Proposed Service Reduces Premature Death and the Economic Loss Associated with Disease

A literature review was conducted to assess whether AB 2174 could result in a decrease in premature death and the economic loss associated with disease. The health outcomes associated with utilization of amino acid–based elemental formula are primarily a decrease in gastrointestinal symptoms and shorter duration of parenteral nutrition but not increased survival or decreased mortality. As such, AB 2174 is not expected to result in a reduction in premature death.

Little research was identified detailing the economic costs associated with diseases and conditions related to AB 2174. The only relevant studies found were those that discussed the costs associated with Crohn's disease, which in severe cases can result in SBS. Bodger (2002) described the indirect costs attributed to Crohn's disease, which reduced productivity due to absenteeism. Yu et al. (2008) estimated that 28% of the total costs associated with Crohn's disease was due to indirect costs, amounting to over $25,000 per patient per year in the United States.

In spite of the lack of research in this area, it is reasonable to assume that there are substantial economic costs attributed to eosinophilic disorders and SBS, where persons and parents are absent from work and school due to lost time associated with illness and seeking treatment. The utilization of amino acid–based elemental formula may help ameliorate those costs by controlling symptoms. However, since AB 2174 is not expected to increase overall utilization of amino acid–based elemental formula, it is not expected to reduce the economic costs associated with eosinophilic disorders and SBS.

APPENDICES

Appendix A: Text of Bill Analyzed

BILL NUMBER: AB 2174 INTRODUCED
BILL TEXT

INTRODUCED BY Assemblyembers Laird and Emmerson

FEBRUARY 20, 2008

An act to add Section 1367.27 to the Health and Safety Code, and to add Section 10123.197 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 2174, as introduced, Laird. Amino based elemental formulas.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the 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.

This bill would require specified health care service plan contracts and health insurance policies to provide coverage for the use of amino 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 based elemental formula is medically necessary.

Because a willful violation of the bill's provisions relative to health care service plans 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. State-mandated local program: yes.

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

SECTION 1. Section 1367.27 is added to the Health and Safety Code, to read:

1367.27. Every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, renewed, or delivered on or after January 1, 2009, that provides coverage for hospital, medical, or surgical expenses shall provide coverage for the use of amino 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 based elemental formula is medically necessary.

SEC. 2. Section 10123.197 is added to the Insurance Code, to read:

10123.197. (a) Every health insurance policy issued, amended, renewed, or delivered on or after January 1, 2009, that provides coverage for hospital, medical, or surgical expenses shall provide coverage for the use of amino 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 based elemental formula is medically necessary.

(b) This section shall not apply to Medicare supplement, short-term limited duration health insurance, vision-only, dental-only, or CHAMPUS supplement insurance, or to hospital indemnity, hospital-only, accident-only, or specified disease insurance that does not pay benefits on a fixed benefit, cash payment only basis.

SEC. 3. 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

Appendix B describes methods used in the medical effectiveness literature review for AB 2174, a bill that would require health plans and health insurance policies to provide coverage for the use of amino acid–based elemental formulas for the diagnosis and treatment of eosinophilic disorders and short bowel syndrome (SBS).

Current health plan policy directives restrict coverage for amino acid–based elemental formula for these conditions to cases that require elemental formula–feeding after surgical procedures that institute nasogastric intubation or the use of a gastric feeding tube. Individuals with SBS receive nutrition management through three stages that encompass parenteral (intravenous) nutrition, enteral nutrition (requiring tube feeding), and introduction of solid foods. Eosinophilic disorders may require nutrition therapy with amino acid–based elemental formula either through enteral or oral feeding. Experts often recommend treating those with eosinophilic disorders with an elimination diet (i.e., eliminating those foods that are causing allergic symptoms), because an elimination diet is more palatable than elemental formula and would likely engender more compliance. However, many patients require an elemental diet approach as often all allergic foods cannot be identified. CHBRP focuses this review of the literature on the effectiveness of the use of amino acid–based elemental formula ingested enterally as an initial step toward oral feeding.

A medical librarian conducted a literature search to retrieve journal articles on the effects of amino acid–based elemental formula on health outcomes for person with eosinophilic disorders and SBS. Due to the rarity of eosinophilic disorders and SBS in the general population, CHBRP included all types of studies in its literature search regardless of their research designs. The most important criterion for inclusion in the literature review is that the study discussed amino acid–based elemental formula and not other forms of treatment for eosinophilic disorders or SBS, such as pharmacotherapy or medical procedures.

For all topics, the literature search was limited to effectiveness studies published in English. The search encompassed all pertinent studies published from 1997 to present. The following databases that index peer-reviewed literature were searched: PubMed, the Web of Science, Cochrane Register of Controlled Clinical Trials, and Cochrane Database of Systematic Reviews. Web sites maintained by the following organizations that publish systematic reviews and evidence-based guidelines were searched: National Guideline Clearinghouse, International Network of Agencies for Health Technology Assessment, National Institute for Clinical Excellence, NHS Centre for Reviews and Dissemination, Scottish Intercollegiate Guideline Network, Agency for Healthcare Research and Quality, National Institutes of Health, and Institute for Clinical Systems Improvements.

The literature search yielded a total of 65 abstracts regarding the effectiveness of amino acid–based elemental formula for the treatment of eosinophilic disorders and SBS. At least two reviewers screened the title and abstract of each citation returned by the literature search to determine eligibility for inclusion. The reviewers obtained the full text of articles that appeared to be eligible for inclusion in the review and reapplied the initial eligibility criteria.

Eosinophilic esophagitis (EE) is the only eosinophilic disorder for which literature on the effectiveness of amino acid–based elemental formula was retrieved. Fourteen studies met the inclusion criteria and were included in the medical effectiveness review.

The medical effectiveness review summarized findings from four articles that addressed elemental formula as treatment for EE and three articles that addressed elemental formula as treatment for SBS. Two of the four articles on EE are nonrandomized studies with comparison groups and two are case series (i.e., no comparison group—all subjects treated with elemental formula). Two of the three articles on SBS are case series and one is a case report.

In making a "call" for each outcome measure, the team and the content expert consider the number of studies as well the strength of the evidence. 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
- 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
- Ambiguous/conflicting evidence
- Insufficient evidence

The conclusion states that there is "clear and convincing" evidence that an intervention has a favorable effect on an outcome, if most of the studies included in a review are well-implemented randomized controlled trials and report statistically significant and clinically meaningful findings that favor the intervention.

The conclusion characterizes the evidence as "preponderance of evidence" that an intervention has a favorable effect if most but not all five criteria are met. For example, for some interventions the only evidence available is from nonrandomized studies or from small RCTs with weak research designs. If most such studies that assess an outcome have statistically and clinically significant findings that are in a favorable direction and enroll populations similar to those covered by a mandate, the evidence would be classified as a "preponderance of evidence favoring the intervention." In some cases, the preponderance of evidence may indicate that an intervention has no effect or has an unfavorable effect.

The evidence is presented as "ambiguous/conflicting" if their findings vary widely with regard to the direction, statistical significance, and clinical significance/size of the effect.

The category “insufficient evidence” of an intervention’s effect is used where there is little if any evidence of an intervention’s effect.

Search Terms

The following search terms were used to retrieve literature pertinent to AB 2174:

amino acid
amino acid–based
amino acid–based formulas
E028 splash
Elecare
elemental diet*
elemental formula*
elemental formulas
eosinophil
eosinophil*
eosinophilia
eosinophilic
eosinophilic colitis
eosinophilic enteritis
eosinophilic esophagitis
eosinophilic gastritis
eosinophilic gastroenteritis
eosinophils, hypereosinophilic
idiopathic eosinophilic esophagitis
Neocate
Nutramigen’
Ross pediatrics
short-gut syndrome
short bowel syndrome
SHS of North America
Tolerex
Vivonex.

* Indicates that a term was truncated to maximize the number of citations retrieved
The terms that are capitalized are either brand names of amino-acid based elemental formulas or names of manufacturers of this type of formula.

Appendix C: Summary Findings on Medical Effectiveness of Amino Acid–Based Elemental Formula

Appendix C describes the studies on the use of amino acid–based elemental formula (and its treatment effects) analyzed by the medical effectiveness team. Tables C-1-a and C-2-a present information regarding the citation, type of study, intervention and comparison groups, population studied, and the location at which a study was conducted. Tables C-2-a and C-2-b summarize findings from the studies reviewed.

Table C-1-a. Summary of Published Studies on Effectiveness of Amino Acid–Based Elemental Formula for Diagnosis and Treatment of Eosinophilic Esophagitis

Citation	Type of Study Design	Intervention	Population Studied	Location
Kagalwalla et al., 2006	Retrospective observational study	Amino acid–based elemental formula vs. 6-food elimination diet	60 children diagnosed with eosinophilic esophagitis	U.S. (Chicago)
Kelly et al., 1995	Case series	Amino acid–based elemental formula	10 children diagnosed with GERD[13] and co-diagnosed with eosinophilic esophagitis	U.S. (Baltimore)
Liacouras et al., 2005	Retrospective study	Amino acid–based elemental formula vs. food elimination diet	160 children treated with elemental formula, 75 children treated with food elimination diet	U.S. (Philadelphia)
Markowitz et al., 2003	Case series	Amino acid–based elemental formula	51 children diagnosed with eosinophilic esophagitis and treated with elemental formula	U.S. (Philadelphia)

[13] Gastroesophageal reflux disease

Table C-1-b. Summary of Findings from Studies of the Effectiveness of Amino Acid–Based Elemental Formula for Diagnosis and Treatment of Eosinophilic Esophagitis

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Resolution of symptoms (vomiting, abdominal pain, dysphagia) Improvement of esophageal histology (number of eosinophils visible upon biopsy)	1 retrospective observational study	• Statistically significant	Better	• After treatment with elemental formula, 15/25 children resolved vomiting, 4/25 resolved abdominal pain, 2/25 children resolved dysphagia • After treatment with 6-food elimination diet, 15/35 children resolved vomiting, 8/35 resolved abdominal pain, 8/35 children resolved dysphagia • Peak eosinophil counts[14] for children treated with elemental formula: pre-treatment 58.8 $\pm$ 31.9; post-treatment 3.6 $\pm$ 6.5 • Peak eosinophil counts[7] for children treated with 6-food elimination diet: pre-treatment 80.2 $\pm$ 44.0; post-treatment 13.6 $\pm$ 23.8	• Somewhat generalizable: U.S. population, small sample size (n=60)	• Evidence from a retrospective study suggests that treatment with 6-food elimination diet or elemental formula improves clinical symptoms and esophageal histology

[14] $\leq$10 eosinophil/HPF = significant improvement; eosinophilic esophagitis is a condition characterized by the presence of excess eosinophils (a type of white blood cell) in the esophagus

Table C-1-b. Summary of Findings from Studies of the Effectiveness of Amino Acid–Based Elemental Formula for Diagnosis and Treatment of Eosinophilic Esophagitis (cont'd)

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Resolution of symptoms (poor weight gain, diarrhea, food refusal, mucous emesis, abdominal pain) Improvement of esophageal histology (number of eosinophils visible upon biopsy)	1 case series	• Statistically significant	• Better	• Resolution of symptoms: n =8 • Improvement of symptoms: n = 2 • *Pre-formula:* maximal esophageal eosinophil count: median # of esophageal eosinophils/HPF: 41 (range: 15-100) • *Post-formula:* maximal esophageal eosinophil count: median # of esophageal eosinophils/HPF: 0.5 (range: 0-22)	• Somewhat generalizable: U.S. population, small sample size (n=10)	• Evidence from one study suggests that treatment of eosinophilic esophagitis with elemental formula is effective and resolves clinical symptoms and esophageal histology

Table C-1-b. Summary of Findings from Studies of the Effectiveness of Amino Acid–Based Elemental Formula for Diagnosis and Treatment of Eosinophilic Esophagitis (cont'd)

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Resolution of symptoms (GER[15] symptoms, dysphagia) Improvement of esophageal histology (number of eosinophils visible upon biopsy)	1 retrospective study	• Statistically significant	• Better	• **Elemental formula** *Pre-formula:* # *with GER* symptoms: 134 # with dysphagia: 30 average # of esophageal eosinophils/HPF: 38.7± 10.3 *Post-formula:* # with GER symptoms: 3 # with dysphagia: 1 average # of esophageal eosinophils/HPF: 1.1± 0.6 • **Food elimination diet** *Pre-diet:* # with GER symptoms: 54 # with dysphagia: 21 average # of esophageal eosinophils/HPF: 47.5 ± 12.1 *Post-diet:* # with GER symptoms: 2 # with dysphagia: 1 average # of esophageal eosinophils/HPF: 5.3 ± 2.7	• Generalizable: U.S. population (sample size: n=160)	• Evidence from a retrospective study suggests that strict use of elemental formula is effective and resolves clinical symptoms and esophageal histology • Evidence from a retrospective study suggests that food elimination diet improves clinical symptoms and esophageal histology

[15] GER = gastroesophageal reflux

Table C-1-b. Summary of Findings from Studies of the Effectiveness of Amino Acid–Based Elemental Formula for Diagnosis and Treatment of Eosinophilic Esophagitis (cont'd)

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Resolution of symptoms (vomiting, abdominal pain, heartburn, water brash, globus, dysphagia, chest pain, night cough, irritability) Improvement of esophageal histology (number of eosinophils visible upon biopsy)	1 case series	• Statistically significant	• Better	*Pre-formula:* # with abdominal pain: 40 # with vomiting: 36 # with heartburn: 27 # with water brash: 11 # with globus: 9 # with dysphagia: 7 # with chest pain: 4 # with night cough: 5 # with irritability: 3 median # of esophageal eosinophils/HPF: 33.7 $\pm$ 10.3 *Post-formula:* # with abdominal pain: 2 # with vomiting: 1 # with heartburn: 2 # with water brash: 1 # with globus: 1 # with dysphagia: 0 # with chest pain: 0 # with night cough: 1 # with irritability: 0 median # of esophageal eosinophils/HPF: 1.0 $\pm$ 0.6	• Somewhat generalizable: U.S. population, small sample size (n=51)	• Evidence from one study suggests that elemental formula significantly improves both clinical symptoms and histological evidence of disease in children and adolescents with eosinophilic esophagitis

Table C-2-a. Summary of Published Studies on Effectiveness of Amino Acid–Based Elemental Formula for Treatment of Short Bowel Syndrome

Citation	Type of Study Design	Intervention	Population Studied	Location
Andorsky et al., 2001	Retrospective medical record review	Amino acid–based elemental formula	30 neonates dependent on parenteral nutrition after surgical therapy for congenital or acquired short bowel syndrome	U.S. (Boston)
Bines et al., 1998	Case series	Amino acid–based elemental formula	4 children aged 23 months – 4.75 years on parenteral nutrition (PN)	Australia
Hasosah et al., 2008	Case report	Amino acid–based elemental formula	1 6-week-old male	Canada

Table C-2-b. Summary of Findings from Studies of the Effectiveness of Amino-Acid Based Elemental Formula for Treatment of Short Bowel Syndrome

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Duration of parenteral nutrition (PN)	Retrospective medical record review[16]	• Statistically significant	• Better	• Feeding with elemental formula is associated with shorter duration of parenteral nutrition (PN): r =-0.793[17]	• Somewhat generalizable: US population, but small sample size (n=30)	• Evidence from one study suggests elemental formula decreases duration of parenteral nutrition (PN), signifying intestinal adaptation[18] necessary for oral feeding
Oral intake/feeding	Case report	• No formal test of statistical significance	• Better	• At eight months of age, child received 70% of his total caloric requirements through enteral feeding (tube feeding), and 30% from parenteral nutrition (intravenous) • At 24 months of age, child was on a regular oral diet	• Limited because only enrolled one subject	• Findings from one case report suggests that elemental formula facilitates transition to oral feeding

[16] Andorsky et al., 2001

[17] If r = -1, there is a perfect negative correlation. If r falls between -1 and -0.5, there is a strong negative correlation.

[18] Short bowel syndrome is a malabsorptive state resulting from congenital malformation of the gut or occurring after extensive resection of the small intestine for acquired lesions. The state of malabsorption becomes critical when the affected individual is unable to maintain hydration and/or nutrient balance and requires the use of supplemental parenteral or enteral nutrition. Intestinal adaptation is the process by which the intestine functionally changes to address the increased nutrient needs of the body, and is a therapeutic aim when treating short bowl syndrome.

Table C-2-b. Summary of Findings from Studies of the Effectiveness of Amino-Acid Based Elemental Formula for Treatment of Short Bowel Syndrome (cont'd)

Outcome	Research Design	Statistical Significance	Direction of Effect	Size of Effect	Generalizability	Conclusion
Duration of parenteral nutrition (PN) Severity and reduction of symptoms (diarrhea and vomiting) and co-morbidities Intestinal permeability[11]	Case series[19]	• Not statistically significant	• Better	• Resolution of diarrhea and vomiting; parenteral nutrition (PN) stopped at 15 months • Reduction in hospitalization (mean: 198 vs. 98 days/patient/year) • Reduction in episodes of bacterial sepsis (mean: 4.3 vs. 3.3/patient/year) • Reduction in central line insertions (mean: 2.5 vs. 1.5/patient/year) • Decrease in intestinal permeability to lactulose (69% vs. 2.7%)[20] • Disaccharidase levels[13] increased in all three patients undergoing repeat studies	• Somewhat generalizable: Australian population and small sample size (n=4)	• Evidence from one study suggests elemental formula decreases duration of parenteral nutrition (PN), relieves symptoms and co-morbidities associated with short bowel syndrome, and improves measurements of intestinal function

[19] Bines et al., 1998

[20] Lactulose levels reflect intestinal function status as lactulose levels indicate resolution of absorption and excretion mechanisms central to intestinal permeability. Intestinal permeability is characterized by the status of the intestinal lining. When the intestinal lining becomes damaged, toxins and other damaging particles may pass directly through damaged cells. Disaccharidase levels are also a measure of intestinal function.

Appendix D: Cost Impact Analysis: Data Sources, Caveats, and Assumptions

This appendix describes data sources, as well as general and mandate-specific caveats and assumptions used in conducting the cost impact analysis. For additional information on the cost model and underlying methodology, please refer to the CHBRP Web site at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

The cost analysis in this report was prepared by the Cost Team which consists of CHBRP task force members and staff, specifically from the University of California, Los Angeles, and Milliman Inc. (Milliman). Milliman is an actuarial firm, and it provides data and analyses per the provisions of CHBRP authorizing legislation.

Data Sources

In preparing cost estimates, the Cost Team relies on a variety of data sources as described below.

Private Health Insurance

1. The latest (2005) California Health Interview Survey (CHIS), which is used to estimate insurance coverage for California's population and distribution by payer (i.e., employment-based, privately purchased, or publicly financed). The biannual CHIS is the largest state health survey conducted in the United States, collecting information from over 40,000 households. More information on CHIS is available at www.chis.ucla.edu/

2. The latest (2007) California Employer Health Benefits Survey is used to estimate:

    - size of firm,
    - percentage of firms that are purchased/underwritten (versus self-insured),
    - premiums for plans regulated by the Department of Managed Health Care (DMHC) (primarily health maintenance organizations [HMOs]),
    - premiums for policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs]), and
    - premiums for high-deductible health plans (HDHPs) for the California population covered under employment-based health insurance.

    This annual survey is released by the California Health Care Foundation/National Opinion Research Center (CHCF/NORC) and is similar to the national employer survey released annually by the Kaiser Family Foundation and the Health Research and Educational Trust. Information on the CHCF/NORC data is available at www.chcf.org/topics/healthinsurance/index.cfm?itemID=133543.

3. Milliman data sources are relied on to estimate the premium impact of mandates. Milliman's projections derive from the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by many of the major health plans in the United States. See www.milliman.com/expertise/healthcare/products-tools/milliman-care-guidelines/index.php. Most of the data sources underlying the HCGs are claims databases

from commercial health insurance plans. The data are supplied by health insurance companies, Blues plans, HMOs, self-funded employers, and private data vendors. The data are mostly from loosely managed healthcare plans, generally those characterized as preferred provider plans or PPOs. The HCGs currently include claims drawn from plans covering 4.6 million members. In addition to the Milliman HCGs, CHBRP's utilization and cost estimates draw on other data, including the following:

- The MEDSTAT MarketScan Database, which includes demographic information and claim detail data for approximately 13 million members of self-insured and insured group health plans.
- An annual survey of HMO and PPO pricing and claim experience. The most recent survey (2006 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2005 experience.
- Ingenix MDR Charge Payment System, which includes information about professional fees paid for healthcare services, based upon approximately 800 million claims from commercial insurance companies, HMOs, and self-insured health plans.

These data are reviewed for applicability by an extended group of experts within Milliman but are not audited externally.

4. An annual survey by CHBRP of the seven largest providers of health insurance in California (Aetna, Blue Cross of California, Blue Shield of California, CIGNA, Health Net, Kaiser Foundation Health Plan, and PacifiCare) to obtain estimates of baseline enrollment by purchaser (i.e., large and small group and individual), type of plan (i.e., DMHC- or CDI-regulated), cost-sharing arrangements with enrollees, and average premiums. Enrollment in these seven firms represents 97% of privately insured enrollees in full-service health plans regulated by DMHC and 88% of those privately insured by comprehensive health insurance products regulated by CDI.

Public Health Insurance

5. Premiums and enrollment in DMHC- and CDI-regulated plans by self-insured status and firm size are obtained annually from CalPERS for active state and local government public employees and their family members who receive their benefits through CalPERS. Enrollment information is provided for fully funded, Knox-Keene licensed health care service plans covering non-Medicare beneficiaries—which is about 75% of CalPERS total enrollment. CalPERS self-funded plans—approximately 25% of enrollment—are not subject to state mandates. In addition, CHBRP obtains information on current scope of benefits from health plans' evidence of coverage (EOCs) publicly available at www.calpers.ca.gov.

6. Enrollment in Medi-Cal Managed Care (Knox-Keene licensed plans regulated by DMHC) is estimated based on CHIS and data maintained by the Department of Health Care Services (DHCS). DHCS supplies CHBRP with the statewide average premiums negotiated for the Two-Plan Model, as well as generic contracts that summarize the current scope of benefits. CHBRP assesses enrollment information available online at www.dhs.ca.gov/admin/ffdmb/mcss/RequestedData/Beneficiary%20files.htm.

7. Enrollment data for other public programs —Healthy Families, Access for Infants and Mothers (AIM), and the Major Risk Medical Insurance Program (MRMIP) —are estimated based on CHIS and data maintained by the Major Risk Medical Insurance Board (MRMIB). The basic minimum scope of benefits offered by participating plans under these programs must comply with all requirements of the Knox-Keene Act, and thus these plans are affected by changes in coverage for Knox-Keene licensed plans. CHBRP does not include enrollment in the Post-MRMIB Guaranteed-Issue Coverage Products as these individuals are already included in the enrollment for individual health insurance products offered by private carriers. Enrollment figures for AIM and MRMIP are included with enrollment for Medi-Cal in presentation of premium impacts. Enrollment information is obtained online at www.mrmib.ca.gov/. Average statewide premium information is provided to CHBRP by MRMIB staff.

General Caveats and Assumptions

The projected cost estimates are estimates of the costs that would result if a certain set of assumptions were exactly realized. Actual costs will differ from these estimates for a wide variety of reasons, including:

- Prevalence of mandated benefits before and after the mandate may be different from CHBRP assumptions.
- Utilization of mandated services before and after the mandate may be different from CHBRP assumptions.
- Random fluctuations in the utilization and cost of health care services may occur.

Additional assumptions that underlie the cost estimates presented in this report are:

- Cost impacts are shown only for people with insurance and only for the first year after enactment of the proposed mandate.
- The projections do not include people covered under self-insured employer plans because those plans are not subject to state-mandated minimum benefit requirements.
- Employers and employees will share proportionately (on a percentage basis) in premium rate increases resulting from the mandate. In other words, the distribution of premium paid by the subscriber (or employee) and the employer will be unaffected by the mandate.
- For state-sponsored programs for the uninsured, the state share will continue to be equal to the absolute dollar amount of funds dedicated to the program.
- When cost savings are estimated, they reflect savings realized for one year. Potential long-term cost savings or impacts are estimated if existing data and literature sources are available and provide adequate detail for estimating long-term impacts. For more information on CHBRP's criteria for estimating long-term impacts please see: http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php
- Several recent studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew et al., 2003; Hadley, 2006; Glied and Jack, 2003). Chernew et al. estimate that a 10% increase in private premiums results in a 0.74 to 0.92 percentage point decrease in the number of insured, while Hadley (2006) and Glied and

Jack (2003) estimate that a 10% increase in private premiums produces a 0.88 and 0.84 percentage point decrease in the number of insured, respectively. The price elasticity of demand for insurance can be calculated from these studies in the following way. First, take the average percentage point decrease in the number of insured reported in these studies in response to a 1-percent increase in premiums (about -0.088), divided by the average percentage of insured individuals (about 80%), multiplied by 100%, i.e., ({[-0.088/80] x 100} = -0.11). This elasticity converts the *percentage point* decrease in the number of insured into a *percentage* decrease in the number of insured for every 1% increase in premiums. Because each of these studies reported results for the large-group, small-group, and individual insurance markets combined, CHBRP employs the simplifying assumption that the elasticity is the same across different types of markets. For more information on CHBRP's criteria for estimating impacts on the uninsured please see http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

- There are other variables that may affect costs, but which CHBRP did not consider in the cost projections presented in this report. Such variables include, but are not limited to:
- Population shifts by type of health insurance coverage: If a mandate increases health insurance costs, then some employer groups and individuals may elect to drop their coverage. Employers may also switch to self-funding to avoid having to comply with the mandate.
- Changes in benefit plans: To help offset the premium increase resulting from a mandate, health plan members may elect to increase their overall plan deductibles or copayments. Such changes would have a direct impact on the distribution of costs between the health plan and the insured person, and may also result in utilization reductions (i.e., high levels of patient cost sharing result in lower utilization of health care services). CHBRP did not include the effects of such potential benefit changes in its analysis.
- Adverse selection: Theoretically, individuals or employer groups who had previously foregone insurance may now elect to enroll in an insurance plan postmandate because they perceive that it is to their economic benefit to do so.
- Health plans may react to the mandate by tightening their medical management of the mandated benefit. This would tend to dampen the CHBRP cost estimates. The dampening would be more pronounced on the plan types that previously had the least effective medical management (i.e., PPO plans).
- Variation in existing utilization and costs, and in the impact of the mandate, by geographic area and delivery system models: Even within the plan types CHBRP modeled (HMO—including HMO and point of service (POS) plans—and non-HMO—including PPO and fee for service (FFS) policies), there are likely variations in utilization and costs by these plan types. Utilization also differs within California due to differences in the health status of the local commercial population, provider practice patterns, and the level of managed care available in each community. The average cost per service would also vary due to different underlying cost levels experienced by providers throughout California and the market dynamic in negotiations between health plans and providers. Both the baseline costs prior to the mandate and the estimated cost impact of the mandate

could vary within the state due to geographic and delivery system differences. For purposes of this analysis, however, CHBRP has estimated the impact on a statewide level

Bill Analysis-Specific Caveats and Assumptions

The estimates of individuals with eosinophilic disorders are obtained from a number of published data sources. The percentage of these individuals using feeding tubes was identified using the following CPT (Current Procedural Terminology) and HCPCS (Healthcare Common Procedure Coding System) codes:

CPT Codes for Eosinophilic Disorders

693.1 Food allergies
530.19 Esophagitis, other
530.10 Esophagitis, unspecified
579.8
558.3
288.3 Eosinophilia
750.3 Esophageal stricture

HCPCS Codes for Eosinophilic Disorders

B4034, B4035, B4036	Enteral feeding supply kits
B4081, B4082, B4083, B4086	Nasogastric, stomach, gastrostomy/jejunostomy tubes
B4100	Food thickener, administered orally, per ounce
B4102	Enteral formula, for adults, used to replace fluids and electrolytes (eg, clear liquids), 500 ml = 1 unit
B4103	Enteral formula, for pediatrics, used to replace fluids and electrolytes (eg, clear liquids), 500 ml = 1 unit
B4104	Additive for enteral formula (e.g., fiber)
B4149-B4162	Enteral formula (administered through an enteral feeding tube)
B9000, B9002	Enteral nutrition infusion pump
S9340-S9343	Home therapy, enteral nutrition

The estimates of individuals with SBS are based on claims data using the following CPT codes provided by the content expert:

CPT Codes for Short Bowel Syndrome

579.3 Short Bowel Syndrome
751.1 Atresia and stenosis of small intestine
751.2 Atresia and stenosis of large intestine
756.79 Other congenital anomalies of abdominal wall
579.8 Other specified intestinal malabsorption
997.4 Intestinal pseudoobstruction

No published estimate of prevalence of this condition was available at the time of CHBRP analysis. The estimate used in this report may overestimate the number individuals with SBS. However, the number of individuals with SBS may be on the rise due to advancements in medical technology.

Appendix E: Information Submitted by Outside Parties

In accordance with CHBRP policy to analyze information submitted by outside parties during the first two weeks of the CHBRP review, the following parties chose to submit information:

No information was submitted directly by interested parties for this analysis.

For information on the processes for submitting information to CHBRP for review and consideration please visit: http://www.chbrp.org/recent_requests/index.php.

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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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