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**CALIFORNIA**  
HEALTH BENEFITS REVIEW PROGRAM

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

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

CHBRP 09-03



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](http://www.chbrp.org).

# **A Report to the 2009-2010 California State Legislature**

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

**March 30, 2009**

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## PREFACE

This report provides an analysis of the medical, financial, and public health impacts of Assembly Bill 163, a bill to mandate the coverage of amino acid–based elemental formulas, regardless of the delivery method, for the diagnosis and treatment of eosinophilic gastrointestinal disorders. In response to a request from the California Assembly Committee on Health on January 29, 2009, 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 163: Coverage for Amino Acid–Based Elemental Formulas

The California Legislature has asked the California Health Benefits Review Program (CHBRP) to conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 163. As introduced by Assembly Member Emmerson on January 27, 2009, this bill would mandate coverage of “amino acid–based elemental formulas, regardless of the delivery method, for the diagnosis and treatment of eosinophilic gastrointestinal disorders when the prescribing physician has issued a written order stating that the amino acid–based formula is medically necessary.” AB 163 would add Section 1367.27 to the Health and Safety Code, and Section 10123.197 to the Insurance Code.

Amino acid–based elemental formulas are complete nutrition formulas designed for individuals who have an immune response to allergens found in whole foods or formulas composed of whole proteins, fats, and/or carbohydrates.

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

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

#### Medical Effectiveness

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

#### Eosinophilic Esophagitis (EE)

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

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<sup>1</sup> People with dysphagia have difficulty swallowing and may also experience pain while swallowing.



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

### Eosinophilic Gastroenteritis (EG)

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

### **Utilization, Cost, and Coverage Impacts**

#### Coverage

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

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

### Utilization

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

- Baseline utilization levels are based on the upper bound estimates of formula use per individual because claims data or published research are not available on exact utilization levels.
- AB 163 does not preclude carriers from charging copayments, coinsurance, deductible, or other cost sharing for this benefit as is done for most currently covered services. The bill also does not preclude carriers from conducting health plan utilization or medical-necessity reviews for coverage of formula to be taken orally.

### Costs

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

### **Public Health Impacts**

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

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

|  | Before Mandate          | After Mandate           | Increase/<br>Decrease | Change<br>After<br>Mandate |
|--|-------------------------|-------------------------|-----------------------|----------------------------|
| <b>Coverage</b>  |                         |                         |                       |                            |
| Total population in plans subject to state regulation (a)  | 21,340,000              | 21,340,000              | 0                     | 0.0%                       |
| Total population in plans subject to AB 163  | 21,340,000              | 21,340,000              | 0                     | 0.0%                       |
| Percentage of individuals with coverage  |                         |                         |                       |                            |
| Formula used with a feeding tube   | 99%                     | 100%                    | 1%                    | 0.8%                       |
| Formula used without a feeding tube  | 35%                     | 100%                    | 65%                   | 182.5%                     |
| Number of individuals with coverage  |                         |                         |                       |                            |
| Formula used with a feeding tube   | 21,161,800              | 21,340,000              | 178,200               | 0.8%                       |
| Formula used without a feeding tube  | 7,553,800               | 21,340,000              | 13,786,200            | 182.5%                     |
| <b>Utilization and Cost</b>  |                         |                         |                       |                            |
| Number of members using formula with a feeding tube  |                         |                         |                       |                            |
| As a covered benefit   | 300                     | 303                     | 3                     | 0.8%                       |
| As a noncovered benefit  | 3                       | 0                       | -3                    | -100%                      |
| Total  | 303                     | 303                     | 0                     | 0.0%                       |
| Number of members using formula orally   |                         |                         |                       |                            |
| As a covered benefit   | 335                     | 947                     | 612                   | 183%                       |
| As a noncovered benefit  | 612                     | 0                       | -612                  | -100%                      |
| Total  | 947                     | 947                     | 0                     | 0.0%                       |
| Average annual formula cost per user   | \$13,900                | \$13,900                | \$0                   | 0.0%                       |
| <b>Expenditures</b>  |                         |                         |                       |                            |
| Premium expenditures by private employers for group insurance  | \$50,546,207,000        | \$50,552,519,000        | \$6,312,000           | 0.0125%                    |
| Premium expenditures for individually purchased insurance  | \$5,944,229,000         | \$5,944,945,000         | \$716,000             | 0.0120%                    |
| Premium expenditures by individuals with group insurance, CalPERS, Healthy Families, AIM, or MRMIP (b) | \$13,475,994,000        | \$13,477,687,000        | \$1,693,000           | 0.0126%                    |
| CalPERS employer expenditures (c)  | \$3,161,160,000         | \$3,161,638,000         | \$478,000             | 0.0151%                    |
| Medi-Cal state expenditures (d)  | \$4,112,865,000         | \$4,112,865,000         | \$0                   | 0.0000%                    |
| Healthy Families state expenditures  | \$643,247,000           | \$643,247,000           | \$0                   | 0.0000%                    |
| Individual out-of-pocket expenditures for covered benefits (deductibles, copayments, etc.)             | \$6,384,077,000         | \$6,384,799,000         | \$722,000             | 0.0113%                    |
| Out-of-pocket expenditures for non-covered benefits  | \$8,543,000             | \$0                     | -\$8,543,000          | -100%                      |
| <b>Total Annual Expenditures</b>   | <b>\$84,276,322,000</b> | <b>\$84,277,700,000</b> | <b>\$1,378,000</b>    | <b>0.0016%</b>             |

Source: California Health Benefits Review Program, 2009.

Notes: (a) This population includes privately insured (group and individual) and publicly insured (e.g., CalPERS, Medi-Cal, Healthy Families, AIM, MRMIP) individuals enrolled in health insurance products regulated by DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment sponsored insurance; (b) Premium expenditures by individuals include employee contributions to employer-sponsored health insurance and member contributions to public insurance; (c) Of the \$478,000 in added CalPERS employer expenditures, about 59% or \$282,020 would be state expenditures for CalPERS members who are state employees; (d) Medi-Cal state expenditures for members under 65 years of age include expenditures for 7,000 newly covered by the Major Risk Medical Insurance Program (MRMIP) and 7,000 newly covered in the Access for Infants and Mothers (AIM) program; Key: CalPERS = California Public Employees' Retirement System.

## INTRODUCTION

Assembly Bill (AB) 163, introduced by Assembly Member Bill Emerson, would mandate coverage of “amino acid–based elemental formulas, regardless of the delivery method, for the diagnosis and treatment of eosinophilic gastrointestinal disorders when the prescribing physician has issued a written order stating that the amino acid–based formula is medically necessary.”

Amino acid–based elemental formulas are complete nutrition formulas designed for individuals who have an immune response to allergens found in whole foods or formulas composed of whole proteins, fats, and/or carbohydrates.

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

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

The California Health Benefits Review program (CHBRP) undertook an analysis of AB 163 in response to a request from the California Assembly Committee on Health on January 29, 2009, 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 163 would add Section 1367.27 to the Health and Safety Code, and Section 10123.197 to the Insurance Code. Last year, CHBRP analyzed a legislative proposal to mandate coverage for amino acid–based elemental formulas (AB 2174, Laird). The only difference between AB 163 and AB 2174 is that AB 163 mandates coverage for persons with EGID, whereas AB 2174 mandated coverage for persons with eosinophilic disorders and short bowel syndrome.

### **Amino Acid–Based Elemental Formulas**

Amino acid–based elemental formulas are one form of treatment for EGID. Elemental formulas are complete nutritional formulas designed for individuals who have an immune response to allergens found in whole foods or formulas composed of whole proteins, fats, and/or carbohydrates. 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) nonallergenic 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 163**

Those primarily affected by AB 163 are persons with EGID who use amino acid–based elemental formulas. There are six eosinophilic disorders of the intestinal track: eosinophilic esophagitis, eosinophilic gastritis, eosinophilic gastroenteritis, eosinophilic enteritis, eosinophilic colitis, and eosinophilic duodenitis. These disorders are caused by the presence of 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.

Few population-based prevalence estimates are available. Eosinophilic esophagitis (EE) is the only EGID for which prevalence estimates have been reported (Furuta et al., 2008). Prevalence estimates of EE vary substantially depending on the population being studied, the technique used for analysis, and the criteria used for determining a diagnosis of EE. A study in Western Australia found a 2004 prevalence of 0.89 cases per 10,000 children. Another study in Ohio found a prevalence of 4.3 per 10,000 children aged 0 to 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, although presumably not all of these individuals were sufficiently symptomatic to seek medical attention.

Another approach to describing the population with EE is to examine what proportion of patients with certain treatments and/or symptoms can be diagnosed with EE. Kapel et al. (2008) reviewed a cohort of upper endoscopy cases (primarily adult cases) from a United States national pathology database and found that 0.5% of those who received an upper endoscopy met the diagnostic criteria for an EE diagnosis. The same rate of 0.5% was found for California patients (Kapel et al., 2008). Another study analyzed a cohort of upper endoscopy adult patients in a tertiary care military hospital and found that 6.5% met the diagnostic criteria for EE (Veerappan et al., 2008). Mackenzie et al. (2008) analyzed upper endoscopies of adults presenting with dysphagia and found that 12% were diagnosed with EE.

A substantial increase in EE prevalence has been found in recent years (Cherian et al., 2006; Kapel et al., 2008; Noel et al., 2004). Noel et al. (2004) found a four-fold increase in children 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).

## **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).<sup>2</sup>

## **State Activities**

Persons with EGID 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: California Children's Services and Women, Infants, and Children.

### California Children's Services (CCS)

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.<sup>3</sup>

The program services persons who:

- are under 21 years old;
- have a medical condition that is covered by CCS;
- are residents of California; and
- 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<sup>4</sup>, or a child with Healthy Families coverage.

### Women, Infants, and Children (WIC) Program

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.

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<sup>2</sup> Health and Safety Code Section 1374.56 and Insurance Code Section 10123.89

<sup>3</sup> "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.

<sup>4</sup> Based on data from the California State Department of Finance, the median household income in California in 2007 was \$55,450. Available at [www.dof.ca.gov/HTML/FS\\_DATA/LatestEconData/FS\\_Income.htm](http://www.dof.ca.gov/HTML/FS_DATA/LatestEconData/FS_Income.htm). Accessed on February 25, 2009. Based on an estimated average annual cost for elemental formula (\$13,900), the out-of-pocket cost for a family with no insurance coverage would be about 25% of median household income.



- 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 \$39,220 for a family of four)<sup>5</sup>.

California WIC serves as a back-up “payer of last resort” for medically necessary formulas in those cases where a WIC participant either is not enrolled in Medi-Cal or where the Medi-Cal/CCS approval process is prolonged.

### **Legislative Activities in Other States**

Nine 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, and eosinophilic disorders. These states are Arizona, Illinois, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, and Rhode Island (See Table 2). In Minnesota, the Minnesota Council of Health Plans has entered into a voluntary agreement to provide coverage for amino acid–based elemental formula.<sup>6</sup>

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<sup>5</sup> USDA Food and Nutrition Service, Income Eligibility Guidelines 2008-2009. Available at [www.fns.usda.gov/wic/howtoapply/incomeguidelines.htm](http://www.fns.usda.gov/wic/howtoapply/incomeguidelines.htm). Accessed February 25, 2009.

<sup>6</sup> Correspondence between the Minnesota Council of Health Plans and the Children's Milk Allergy and Gastrointestinal Coalition dated June 20, 2007. Available at [neocate.com/aaa\\_neocate/download/reimbursement/Minnesota%20Agreement%20Letter.pdf](http://neocate.com/aaa_neocate/download/reimbursement/Minnesota%20Agreement%20Letter.pdf). Accessed February 2, 2009.

**Table 2.** Scope of Laws in Other States Mandating Health Insurance Coverage of Amino Acid–Based Elemental Formulas

| State       | Conditions Covered  | Population Covered         | Delivery Method Covered | Benefit Limits/ Cost Sharing  | Citation   |
|-------------|---|----------------------------|-------------------------|---|--|
| Arizona     | <ul style="list-style-type: none"> <li>• <b>Eosinophilic gastrointestinal disorders</b></li> </ul>  | All                        | Oral, feeding tube      | Requires reimbursement of 75% of formula cost; annual benefit cap is \$20,000 | <i>Arizona Revised Statutes</i> ; 20 § 826.03                |
| Connecticut | <ul style="list-style-type: none"> <li>• Cystic fibrosis</li> <li>• Inherited metabolic diseases (these include diseases for which newborn screening is required in CT)</li> </ul>  | Children up to age 12      | Oral, feeding tube      | Does not specify  | <i>General Statutes of Connecticut</i> ; ch. 700c § 38a-518c |
| Illinois    | <ul style="list-style-type: none"> <li>• <b>Eosinophilic disorders</b></li> <li>• Short bowel syndrome</li> </ul>   | All                        | Oral, feeding tube      | Does not specify  | <i>Illinois Compiled Statutes</i> ; 5 § 375/6.11             |
| Maine       | <ul style="list-style-type: none"> <li>• <b>Allergic or eosinophilic gastroenteritis</b></li> <li>• Symptomatic allergic colitis or proctitis</li> <li>• History of anaphylaxis</li> <li>• Gastroesophageal reflux disease (nonresponsive to standard therapies)</li> <li>• Severe vomiting or diarrhea</li> <li>• Cystic fibrosis</li> <li>• Malabsorption of cow milk–based or soy milk–based infant formula</li> </ul> | Children age two and under | Oral, feeding tube      | Coverage is subject to the same limits that apply to overall benefits         | <i>Maine Revised Statutes</i> ; 24-A ch.35 §2847-P           |

**Table 2.** Scope of Laws in Other States Mandating Health Insurance Coverage of Amino Acid–Based Elemental Formulas (Cont’d)

| State         | Conditions Covered   | Population Covered | Delivery Method Covered | Benefit Limits/ Cost Sharing  | Citation  |
|---------------|--|--------------------|-------------------------|---|---|
| Maryland      | <ul style="list-style-type: none"> <li>• <b>Eosinophilic disorders</b></li> <li>• Immunoglobulin E and non-immunoglobulin E mediated allergies to multiple food proteins</li> <li>• Severe food protein induced enterocolitis syndrome</li> <li>• Impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length and motility of the gastrointestinal tract</li> </ul> | All                | Oral, feeding tube      | Does not specify  | <i>Annotated Code of Maryland</i> ; Article Insurance § 15-843            |
| Massachusetts | <ul style="list-style-type: none"> <li>• Crohn’s Disease</li> <li>• Ulcerative colitis</li> <li>• Gastroesophageal reflux</li> <li>• Gastrointestinal motility</li> <li>• Chronic intestinal pseudo-obstruction</li> <li>• Inherited diseases of amino acids and organic acids</li> </ul>  | All                | Does not specify        | Does not specify  | <i>General Laws of the Commonwealth of Massachusetts</i> ; ch. 176A: § 8L |
| New Hampshire | <ul style="list-style-type: none"> <li>• Impaired absorption of nutrients caused by disorders affecting the absorptive surface, functional length, or motility of the gastrointestinal tract.</li> <li>• Inherited diseases of amino acid and organic acids</li> </ul>   | All                | Does not specify        | Coverage is subject to the same limits that apply to overall benefits | <i>New Hampshire Revised Statutes</i> ; Title 37, ch. 415 §18-e           |
| New Jersey    | <ul style="list-style-type: none"> <li>• Multiple food protein intolerance</li> </ul>  | Infants            | Oral, feeding tube      | Coverage is subject to the same limits that apply to overall benefits | <i>New Jersey Permanent Statutes</i> , Title 17 :48-6z                    |

**Table 2.** Scope of Laws in Other States Mandating Health Insurance Coverage of Amino Acid–Based Elemental Formulas (Cont’d)

| State        | Conditions Covered   | Population Covered | Delivery Method Covered | Benefit Limits/ Cost Sharing  | Citation   |
|--------------|--|--------------------|-------------------------|---|--|
| New York     | <ul style="list-style-type: none"> <li>• Inherited diseases of amino acid or organic acid metabolism</li> <li>• Crohn’s Disease</li> <li>• Gastroesophageal reflux</li> <li>• Disorders of gastrointestinal motility such as chronic intestinal pseudo-obstruction multiple severe food allergies</li> </ul> | All                | Does not specify        | Does not specify  | <i>New York State Insurance Law</i> , article 32, § 3216 (i)(21) |
| Rhode Island | <ul style="list-style-type: none"> <li>• Malabsorption caused by Crohn’s disease</li> <li>• Ulcerative colitis</li> <li>• Gastroesophageal reflux</li> <li>• Chronic intestinal pseudo-obstruction</li> <li>• Inherited diseases of amino acids and organic acids</li> </ul>                                 | All                | Does not specify        | Coverage is subject to the same limits that apply to overall benefits | <i>Rhode Island General Laws</i> , Title 27, § 27-19-61          |

Sources: Children’s Milk Allergy and Gastrointestinal Coalition (Children’s MAGIC). *States With Elemental Formula Coverage*. Available at [www.childrensmagic.org/pages/statesresources.html](http://www.childrensmagic.org/pages/statesresources.html). Accessed February 26, 2009.

National Conference of State Legislatures. *Coverage of Medically Necessary Foods and Formula to Treat Disorders Identified Through Newborn Screening*. Available at [www.ncsl.org/programs/health/Lawsfoodsformula.htm](http://www.ncsl.org/programs/health/Lawsfoodsformula.htm). Accessed February 26, 2009.

Neocate. *Reimbursement Legislation*. Available at [neocate.com/aaa\\_neocate/259-products-reimbursement.html](http://neocate.com/aaa_neocate/259-products-reimbursement.html). Accessed February 27, 2009.

## MEDICAL EFFECTIVENESS

AB 163 would require specified health care service plan contracts and health insurance policies to provide coverage for amino acid–based elemental formula for the diagnosis and treatment of EGID. These disorders compromise a person’s ability to ingest food orally. Amino acid–based elemental formula has been investigated as a treatment for these disorders, because elemental formula is hypoallergenic and has simplified nutrient components that facilitate absorption of nutrients. Because literature on the effectiveness of amino acid–based elemental formula for EGID was found only for EE and EG, this section of the report describes the disease pathology and clinical symptoms associated with these conditions and summarizes the evidence of the effectiveness of amino acid–based elemental formula for treating these two disorders.

### Literature Review Methods

The scope of the medical effectiveness literature reviewed for this report included pertinent studies published in English from 1997 to 2009. The literature reviewed includes studies on the use of formula to treat EE that were discussed in CHBRP’s report on AB 2174, a similar bill introduced in 2008, as well as additional studies published since CHBRP issued that report. Specifications were as follows: study populations include both males and females, persons of all ages, and all types of research designs. Five studies of the effectiveness of elemental formula as a treatment for EGID were identified. The medical effectiveness team obtained background information from six additional articles. Further details about the literature review are presented in *Appendix B*.

The low prevalence of EGID affects the scope of the medical effectiveness literature on this topic. Few studies address whether amino acid–based elemental formula is an 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 EGID. Although these disorders affect 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 other treatments for these conditions, such as topical and systemic corticosteroids.

### Findings

#### Eosinophilic Esophagitis (EE)

EE is a disorder in which the number of eosinophils (a type of white blood cell that participates in the immune response to allergens) increases dramatically 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 proinflammatory 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 inadequate weight gain and weight loss among affected children. Most adults, however, present with chronic and intermittent dysphagia, and repeat episodes of food impaction that often require endoscopy to resolve. Persons who are first diagnosed with EE as adults 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 not known 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 dilatation (performed with or without an endoscope) to improve symptoms such as dysphagia (i.e., difficulty in swallowing). The efficacy of treatments for EE 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.

Open-label clinical trials are currently being conducted to assess the efficacy of three biological agents for the treatment of EGID: two humanized monoclonal antibodies against interleukin-5 (IL-5)—mepolizumab and reslizumab—and one against IgE—omalizumab (Stone et al., 2008). Phase I/II clinical trials have demonstrated promising results regarding the efficacy of anti-IL-5 to alleviate symptoms associated with these disorders. However, large phase III trials have yet to be completed. No studies have compared the effectiveness of anti-IL-5 to that of other treatments for EGID, such as corticosteroids, dilatation, or elemental formula.

#### *Amino acid–based elemental formula and eosinophilic esophagitis*

Dietary therapy has become a mainstay of treatment for EE due to the condition's association with food allergies. In addition, treatment with systemic and topical steroids does not always improve symptoms and injury due to inflammation. The inflammatory injury also often recurs when steroid therapy is discontinued, because steroids do not alter the underlying abnormality in immune response (Furuta et al., 2007).

There are two major types of dietary therapy: elimination diets and elemental formula. Elimination diets involve eliminating the food allergens commonly associated with EE (i.e., milk

protein, soy, egg, wheat, peanut/tree nuts, and seafood). Some clinicians prescribe diets that eliminate these six foods without testing patients for allergies to specific foods, because allergy tests are not reliable indicators of foods responsible for EE symptoms (Kagalwalla et al., 2006). Others rely on allergy tests to determine which foods to eliminate (Liacouras et al., 2005). The rationale for using elemental formula in place of elimination diets is that these diets often cannot alleviate symptoms. Elemental formula may be a more effective treatment for some persons because it is hypoallergenic. However, experts report that some persons with EE have difficulty using elemental formula due to the taste<sup>7</sup> (Kagalwalla et al., 2006). Patients and families may find implementing either type of dietary therapy challenging (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). Some persons with EE use both elimination diets and elemental formula. These persons eat foods to which they are not allergic and use elemental formula as a supplement to ensure adequate nutrition. Supplementation is necessary for some persons with EE because the foods eliminated from their diet are major sources of protein and other important nutrients.<sup>7</sup>

#### *Summary of study findings of eosinophilic esophagitis*

Resolution of the aforementioned clinical symptoms was a primary outcome in all studies of the effectiveness of elemental formula as a treatment for EE. 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 (preformula counts = median 41 [range: 15-100]; postformula 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 were significant reductions 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. However, both of these studies were case series that did not include a comparison group of children who were not treated with elemental formula. The studies also enrolled small numbers of children, which may limit the generalizability of their findings.<sup>8</sup>

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

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<sup>7</sup> Personal communication with G Russell, MD, Massachusetts General Hospital, February 2009.

<sup>8</sup> Kelly and colleagues enrolled 10 children and Markowitz and colleagues enrolled 51 children.

esophageal eosinophils/HPF and post-treatment values were (average)  $1.1 \pm 0.6$  esophageal eosinophils/HPF. The patients treated with an elimination diet in which foods were eliminated based on allergy test results 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.

In one study, four of six children whose symptoms were not improved by the elimination diet were subsequently treated with elemental formula. Three of the four children experienced substantial improvements in histology and one experienced partial improvement (Kagawalla et al., 2006).

The only evidence regarding the effectiveness of elemental formula for the treatment of EE comes from studies with weak research designs and small sample sizes. Findings from these studies suggest that amino acid–based elemental formula and elimination diet are both effective strategies to treat EE. The evidence does not indicate which regimen is more effective, although some children whose symptoms did not improve on an elimination diet were treated successfully with elemental formula.

### Eosinophilic Gastroenteritis (EG)

EG is a rare condition involving eosinophilic infiltration in one or more areas of the lower gastrointestinal tract. As in the case of EE, EG is not fully understood. Chehade and colleagues (2007) have proposed that in children this disease is also associated with food allergy, as evidenced by observing the elimination of the food allergic response of EG after treatment with amino acid–based elemental formula (Chehade et al., 2007).

CHBRP identified the only article that addressed the therapeutic effect of elemental formula on EG. Chehade et al. examined the case of an 11-year-old girl who had had multiple food allergies since the age of 3 and an unusual anomalous condition of allergic EG. She had widespread gastric and proximal small intestinal mucosal disease consisting of diffuse ulcerations and pseudopolyps, despite minimal clinical symptoms associated with EG, such as abdominal pain, nausea, vomiting, diarrhea, and weight loss (Chehade, 2007). The child was treated exclusively with an amino acid–based formula (Neocate One Plus) and cooked apple. After 9 weeks of dietary therapy with elemental formula, upon endoscopy her endoscopic and histological abnormalities improved dramatically. The patient’s severe gastrointestinal mucosal ulcers and pseudopolyps resolved almost completely. Histologically, her gastritis improved, with a maximum of 10 eosinophils per HPF. The patient’s swallowing and chewing normalized, and she had no gastrointestinal symptoms and no recurrence of her disease after 9 weeks of dietary therapy.

Evidence regarding the medical effectiveness of elemental formula for the treatment of EG is very limited. Findings from one case report of EG suggest that elemental formula may improve histological abnormalities of gastric and proximal small intestinal mucosal disease. However, findings from this single case may not generalize to other persons with EG.



In conclusion, amino acid–based formula appears to be effective in treating EE and EG, but the evidence of the medical effectiveness of elemental formula for these conditions is based on a small number of studies with weak research designs.

## UTILIZATION, COST, AND COVERAGE IMPACTS

AB 163 would require health plan contracts and policies regulated by the DMHC and health insurance products regulated by the CDI to provide coverage for amino acid–based elemental formulas, regardless of delivery method, for the diagnosis and treatment of EGID, when the prescribing physician has issued a written order stating that the formula is medically necessary. The mandate provides coverage for such formulas taken orally as well as via feeding tube, and applies to enrollees in group (large and small) and individual markets. AB 163 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. 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 first section presents the current, or baseline, costs and coverage of amino acid–based elemental formulas taken orally for individuals with EGID. The report then provides the estimated utilization, cost, and coverage impacts of AB 163. For further details on the underlying data sources and methods, see *Appendix D*.

### **Present Baseline Cost and Coverage**

#### Current Coverage of Mandated Benefit

Approximately 21,340,000 individuals in California are enrolled in health plans or policies that would be affected by this legislation. Currently 99% of individuals with EGID are covered for the use of formula through a feeding tube, and 35% are covered for its use when ingested orally.

CHBRP surveyed the major health plans and insurers regarding coverage.<sup>9</sup> Responses to this survey represented 82% of the CDI-regulated and 98% of the DMHC-regulated market. Combined, responses to this survey represent 96% of the privately insured market. The results suggest that about 25% of persons in 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 of those in CDI-regulated insurance products (55%) are covered than those in DMHC-regulated health plans (20%). Coverage for those in privately insured DMHC-regulated plans ranges from 18% in the large group, 25% in the small group, to 34% in the individual market. In the CDI-regulated market, coverage ranges from 50% in the large-group market, 49% 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.<sup>10</sup>

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<sup>9</sup> Estimates based on 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.

<sup>10</sup> 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

Combining those with private and public insurance, about 35% of the population affected by AB 163 (an estimated 7.5 million people) has coverage for amino acid–based elemental formula taken orally.

The prevalence of EGID is very low, estimated to be approximately 4 per 10,000. These prevalence rates translate into approximately 8,500 persons in California with EGID who would be directly affected by the proposed mandate.<sup>11</sup>

### Current Utilization Levels and Costs of the Mandated Benefit

#### *Current utilization levels*

The percentage of individuals with EGID 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; (4) individuals with eosinophilic disorders may use the oral formula intermittently as their symptoms vary; and (5) these formulas are used to treat other conditions besides EGID. The combination of these problems results in a lack of sufficient and reliable quantitative data on utilization.

Because claims data were not reliable, CHBRP based its utilization estimates on information from a limited number of published studies and from content expert information. For this analysis, CHBRP collected additional information (beyond that collected for the 2008 analysis<sup>12</sup>) from both the literature and expert opinion suggesting that due to poor palatability and lifestyle considerations, the proportion who actually consume formula would be less than the full 25% who could, based on published estimates, benefit from it (Furuta, 2007). The one exception would be infants, where CHBRP could reasonably assume 100% of infants would need the formula and would accept it due to lack of prior established taste preferences.

Therefore, while estimates of the proportion using formula vary widely within and across states, content experts estimated utilization at rates below 25%, ranging from 1% to 15% of people with EGID using elemental formula part-to-full-time. Based on these data, CHBRP used the upper bound value to estimate that 15% of individuals with EGID take formula orally or via tube, either part- or full-time. This percentage represents a weighted average of use among infants, children aged 2 to 17, and adults, all of whom may use formula as either 100% or just as part of

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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.

<sup>11</sup> Prevalence EGID is based on published estimates of EE prevalence in a U.S. study by Noel and colleagues (2004). CHBRP used this estimate for all EGID at all ages. See also explanation of mandate-specific assumptions in *Appendix D*.

<sup>12</sup> For the 2008 analysis (AB 2174), the percentage of individuals using formula was assumed to be 25%, based on published estimates that 74% to 77% of children experienced improvement from an elimination diet, and therefore CHBRP assumed that the remaining 25% would 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).

their diet. CHBRP assumes that 100% of infants would use formula orally as their sole source of nutrition. For children aged 2 to 17, CHBRP estimates that 9% would use formula orally and 6% would use it via feeding tube.

Of children and teens on formula, some consume it as 100% of their diet, some as a partial percent, and some take it orally while others take it via feeding tube. For this 2009 analysis,<sup>13</sup> CHBRP used data from an unpublished analysis conducted at the Cincinnati Center for Eosinophilic Disorders, indicating that of those on formula full-time over the course of a year (15% of youth with EGID), 40% (6% of youth with EGID) received the formula via tube, and the remaining 60% (9% of youth with EGID) take it orally full-time. CHBRP also assumes that an upper bound estimate of 10% of children and teens with EGID consume formula part time for 50% of their daily calories; this estimate represents the 25% who could benefit from it, minus the 15% who consume it full-time. Due to lack of available data on the distribution of tube-versus-oral delivery for part-time formula users, CHBRP assumed that all such users consume it orally.

There are no published studies or claims data on adults' use of formula. Therefore, CHBRP has estimated that 7.5% (half of that for youth) of the adult population is on formula full-time. 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—as well as the likely underdiagnosis of EGID in adults who may be misdiagnosed with reflux or other disorders.

#### *Unit price*

CHBRP estimates an average annual cost of \$13,900 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 were supplied to CHBRP by clinical dietitians involved in the care of individuals with EGID. 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 and thus this number could be an overestimate of total costs.

The baseline costs associated with the mandate given current coverage levels, utilization, and unit price are presented in Table 3.

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

Consumption of oral formula for some individuals is medically necessary and cannot be fully substituted by medication or food avoidance. Discussions with clinicians specializing in care of

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<sup>13</sup> For the 2008 analysis of AB 2174, CHBRP assumed that all consumption was at 100%, and the percentage assumed to be using feeding tubes had been identified using CPT (Current Procedural Terminology) and HCPCS (Healthcare Common Procedure Coding System) codes.

infants and young children with EGID 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 always sustainable and may lead to nutritional deficiencies and inadequate weight gain and growth in young children. Many would remain dependent on these formulas for the long term to ensure adequate nutrition and health. Individuals with EGID also have a choice of keeping the feeding tube in place for as long as use of formula is needed to maximize insurance coverage.

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 unpalatable. Consequently, AB 163 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, because oral formula is currently provided as a benefit to 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 163. 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 the treatment of phenylketonuria (PKU). CalPERS' PPO self-insured plans exclude vitamins, minerals, and nutritional supplements as a covered benefit, whether available over the counter or prescribed by a physician. 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.<sup>14</sup>

To further investigate public demand for benefits addressed by the bill, the CHBRP coverage survey fielded after the bill analysis request was received asked carriers that offer plans or policies to self-insured groups whether the relevant benefits differed from those offered in plans or policies available in the commercial markets. The responding carriers indicated that there were no substantive differences for these benefits between plans and policies available in the commercial market and the plans and policies currently provided to self-insured entities.

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<sup>14</sup> Personal communication with E. Clayton, California Labor Federation, March 2009.

## **Impacts of Mandated Coverage**

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

#### *Impact on supply and on the health benefit*

CHBRP assumes that there would be no impact on the supply or health benefit (i.e., medical effectiveness) due to this mandate.

#### *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 EGID is generally effective. In addition, CHBRP assumes that the level of patient compliance/adherence in use of formulas would not be affected by AB 163. Finally, these disorders are rare and patient demand would not create price pressures post-mandate. Since AB 163 would not affect the effectiveness nor place price pressures on formulas, CHBRP does not anticipate any changes to the per-unit cost of these products due to AB 163.

#### *Post-mandate coverage*

AB 163 would extend coverage to all privately and CalPERS-insured individuals for use of amino acid–based elemental formula taken via feeding tube or ingested orally. CHBRP estimates that 99% of individuals with EGID currently have coverage for the use of formula through a feeding tube, thus coverage increases by 1% for those on feeding tubes. CHBRP estimates that 65% of those ingesting formula orally would gain coverage for this product under AB163, as currently only 35% of this population is covered. When considering all individuals with EGID who use formula, CHBRP estimates that 3 who take it via tube and 612 who ingest it orally would be newly 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, as 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 Would Utilization Change As a Result of the Mandate?

The utilization of amino acid–based elemental formula administered by feeding tube or ingested orally is estimated to remain essentially unchanged under AB 163. The utilization of formula among those with EGID who have a feeding tube would remain unchanged because there are no individuals with the 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 because poor palatability lowers 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 post-mandate for the elemental formula for persons with EGID for several reasons. Based on expert clinical opinion, there is not an underutilization of formula among those who ingest orally. Those with EGID who need 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 may increase utilization under AB 163. In some cases, individuals needing formula may have attempted to use alternatives such as topical steroids, and coverage under AB 163 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 EGID 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 negligible. 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 Would 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 163 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 163, CHBRP estimates an increase of \$1,378,000 in administrative costs—or 0.0016% of expenditures—for plans regulated by the DMHC and CDI.

#### Impact of the Mandate on Total Health Care Costs

##### *Changes in total expenditures*

Currently about \$8,543,000 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 \$1,378,000 (0.0016%) post-mandate.

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

- Employers' (including CalPERS) share of premium increases is estimated to be \$6,312,000 (0.0125%).
- Enrollees in individually purchased plans would face an increase of \$716,000 (0.0120%) in premiums.
- Enrollees' share of premium increases in the group plans is estimated to be \$1,693,000 (0.0126%).
- CalPERS' enrollees share of premium increases is estimated to be \$478,000 (0.0151%).
- Total copayments, deductibles, and other forms of cost sharing by all insured is estimated to increase by \$722,000 (0.0113%).

CHBRP estimates no perceptible savings or offsets in other health care costs due to AB 163 since the bill is not expected to significantly reduce or increase use of other types of health care services.

#### *Impact on long-term costs*

AB 163 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.

#### Impacts for Each Category of Payer Resulting from the Benefit Mandate

##### *Changes in expenditures and PMPM amounts by payer category*

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 0.0130% (\$0.0453 PMPM) in the DMHC-regulated market, and 0.0065% (\$0.0284 PMPM) in the CDI-regulated market.
- Small-group market: an estimated premium increase of 0.0137% (\$0.0437 PMPM) in the DMHC-regulated market, and 0.0067% (\$0.0230 PMPM) in the CDI-regulated market.
- Individual market: an estimated premium increase of 0.0122% (\$0.0402 PMPM) in the DMHC-regulated market, and 0.0118% (\$0.0200 PMPM) in the CDI-regulated individual market.
- CalPERS: an estimated premium increase of 0.0151% (\$0.0572 PMPM).

The projected cost impacts as a result of AB 163 are summarized in Table 4.

##### *Impact of changes in private coverage on public programs*

CHBRP estimates that the mandate would produce no measurable impact on enrollment in public insurance programs or on utilization of covered benefits in the public sector.



### Impact on Access and Health Service Availability

AB 163 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 163 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 because use of them is considered a medical necessity.

### *Consumer complaints*

As of September 2008, the DMHC has received 51,372 complaints since 2001, of which 67 were related 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.<sup>15</sup> The percentage and nature of the complaints related to EGID are unknown.

### *Appeals to the Independent Medical Review Program*

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 163. As of September 2008, DMHC had completed 8,382 independent medical reviews since 2000, and there were no patient disputes regarding the medical necessity of elemental formulas for EGID. Of the eight disputes filed for disorders of the gastrointestinal/digestive system, none were for EGID. Disputes were related to prescription formulas for use of other diagnoses: GERD/Reflux disorders, ulcerative colitis, and Crohn’s disease.

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<sup>15</sup> Personal communication with S Lowenstein, DMHC, February 2009.

**Table 3.** Baseline (Pre-mandate) Per Member Per Month Premium and Expenditures by Market Segment, California, 2009

|  | DMHC-Regulated |             |            |             |                          |                       |                  | CDI-Regulated |             |            | Total Annual     |
|--|----------------|-------------|------------|-------------|--------------------------|-----------------------|------------------|---------------|-------------|------------|------------------|
|  | Large Group    | Small Group | Individual | CalPERS (b) | Medi-Cal (c)             |                       | Healthy Families | Large Group   | Small Group | Individual |                  |
|  |                |             |            | HMO         | Managed Care 65 and Over | Managed Care Under 65 | Managed Care     |               |             |            |                  |
| <b>Total Population in Plans Subject to State Regulation (a)</b> | 11,100,000     | 2,844,000   | 966,000    | 820,000     | 159,000                  | 2,366,000             | 715,000          | 400,000       | 932,000     | 1,038,000  | 21,340,000       |
| <b>Total Enrolled in Plans Subject to AB 163</b>                 | 11,100,000     | 2,844,000   | 966,000    | 820,000     | 159,000                  | 2,366,000             | 715,000          | 400,000       | 932,000     | 1,038,000  | 21,340,000       |
| Average portion of premium paid by Employer                      | \$279.83       | \$246.48    | \$0.00     | \$321.26    | \$239.00                 | \$128.09              | \$74.97          | \$341.25      | \$288.13    | \$0.00     | \$58,443,353,000 |
| Average portion of premium paid by Employee                      | \$69.94        | \$71.52     | \$330.89   | \$56.69     | \$0.00                   | \$0.71                | \$10.22          | \$97.61       | \$54.11     | \$169.28   | \$19,440,350,000 |
| <b>Total Premium</b>   | \$349.77       | \$318.00    | \$330.89   | \$377.95    | \$239.00                 | \$128.80              | \$85.19          | \$438.86      | \$342.24    | \$169.28   | \$77,883,703,000 |
| Member expenses for covered benefits (Deductibles, copays, etc.) | \$18.90        | \$24.61     | \$54.10    | \$19.49     | \$0.00                   | \$0.59                | \$2.32           | \$53.72       | \$124.95    | \$41.39    | \$6,384,077,000  |
| Member expenses for benefits not covered                         | \$0.04         | \$0.04      | \$0.03     | \$0.05      | \$0.00                   | \$0.00                | \$0.00           | \$0.03        | \$0.03      | \$0.02     | \$8,543,000      |
| <b>Total Expenditures</b>  | \$368.72       | \$342.66    | \$385.03   | \$397.49    | \$239.00                 | \$129.39              | \$87.51          | \$492.61      | \$467.22    | \$210.68   | \$84,276,323,000 |

Source: California Health Benefits Review Program, 2009.

Notes: (a) This population includes privately insured (group and individual) and publicly insured (e.g., CalPERS, Medi-Cal, Healthy Families, AIM, MRMIP) individuals enrolled in health insurance products regulated by the DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment sponsored insurance.

(b) Of these CalPERS members, about 59% or 483,800 are state employees.

(c) Medi-Cal state expenditures for members under 65 years of age include expenditures for the Major Risk Medical Insurance Program (MRMIP) and the Access for Infants and Mothers (AIM) program. Medi-Cal state expenditures for members over 65 years of age include those with Medicare coverage.

Key: CalPERS = California Public Employees' Retirement System; HMO = health maintenance organization and point of service plans.

**Table 4.** Impacts on Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2009

|  | DMHC-Regulated |             |            |             |                          |                       |                  | CDI-Regulated |             |            | Total Annual |
|--|----------------|-------------|------------|-------------|--------------------------|-----------------------|------------------|---------------|-------------|------------|--------------|
|  | Large Group    | Small Group | Individual | CalPERS (b) | Medi-Cal (c)             |                       | Healthy Families | Large Group   | Small Group | Individual |              |
|  |                |             |            | HMO         | Managed Care 65 and Over | Managed Care Under 65 | Managed Care     |               |             |            |              |
| <b>Total Population in Plans Subject to State Regulation (a)</b> | 11,100,000     | 2,844,000   | 966,000    | 820,000     | 159,000                  | 2,366,000             | 715,000          | 400,000       | 932,000     | 1,038,000  | 21,340,000   |
| <b>Total Population in Plans Subject to AB 163</b>               | 11,100,000     | 2,844,000   | 966,000    | 820,000     | 159,000                  | 2,366,000             | 715,000          | 400,000       | 932,000     | 1,038,000  | 21,340,000   |
| Average portion of premium paid by Employer                      | \$0.0363       | \$0.0340    | \$0.0000   | \$0.0487    | \$0.0000                 | \$0.0000              | \$0.0000         | \$0.0221      | \$0.0193    | \$0.0000   | \$6,791,000  |
| Average portion of premium paid by Employee                      | \$0.0091       | \$0.0097    | \$0.0402   | \$0.0086    | \$0.0000                 | \$0.0000              | \$0.0000         | \$0.0063      | \$0.0036    | \$0.0200   | \$2,408,000  |
| <b>Total Premium</b>   | \$0.0453       | \$0.0437    | \$0.0402   | \$0.0572    | \$0.0000                 | \$0.0000              | \$0.0000         | \$0.0284      | \$0.0230    | \$0.0200   | \$9,199,000  |
| Member expenses for covered benefits (Deductibles, copays, etc.) | \$0.0025       | \$0.0035    | \$0.0064   | \$0.0030    | \$0.0000                 | \$0.0000              | \$0.0000         | \$0.0035      | \$0.0084    | \$0.0049   | \$722,000    |
| Member expenses for benefits not covered                         | -\$0.0426      | -\$0.0387   | -\$0.0339  | -\$0.0516   | \$0.0000                 | \$0.0000              | \$0.0000         | -\$0.0276     | -\$0.0261   | -\$0.0182  | -\$8,543,000 |
| <b>Total Expenditures</b>  | \$0.0052       | \$0.0085    | \$0.0127   | \$0.0086    | \$0.0000                 | \$0.0000              | \$0.0000         | \$0.0043      | \$0.0053    | \$0.0067   | \$1,378,000  |
| <b>Percentage Impact of Mandate</b>                              |                |             |            |             |                          |                       |                  |               |             |            |              |
| Insured Premiums   | 0.0130%        | 0.0137%     | 0.0122%    | 0.0151%     | 0.0000%                  | 0.0000%               | 0.0000%          | 0.0065%       | 0.0067%     | 0.0118%    | 0.0118%      |
| Total Expenditures   | 0.0014%        | 0.0025%     | 0.0033%    | 0.0022%     | 0.0000%                  | 0.0000%               | 0.0000%          | 0.0009%       | 0.0011%     | 0.0032%    | 0.0016%      |

Source: California Health Benefits Review Program, 2009.

Notes: (a) This population includes privately insured (group and individual) and publicly insured (e.g., CalPERS, Medi-Cal, Healthy Families, AIM, MRMIP) individuals enrolled in health insurance products regulated by the DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment sponsored insurance; (b) Of these CalPERS members, about 59% or 483,800 are state employees; (c) Medi-Cal state expenditures for members under 65 years of age include expenditures for the Major Risk Medical Insurance Program (MRMIP) and the Access for Infants and Mothers (AIM) program. Medi-Cal state expenditures for members over 65 years of age include those with Medicare coverage.

Key: CalPERS = California Public Employees' Retirement System; HMO = health maintenance organization and point of service plans.

## 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 are primarily a decrease in symptoms of EGID (e.g., dysphagia, pain, vomiting) (Markowitz et al., 2003). According to the *Utilization, Cost, and Coverage Impacts* section, AB 163 would not result in an increase in utilization of amino acid–based elemental formula for EGID. AB 163 would, however, increase insurance coverage for this benefit and thus decrease out-of-pocket expenditures to 615 individuals (Table 1<sup>16</sup>). While these 615 individuals are not expected to incur any improved health outcomes due to AB 163, this bill would reduce the financial hardship associated with these disorders, where the average estimated cost of amino acid–based elemental formula is \$13,900 per year.

As mentioned in previous sections of this report, amino acid–based elemental formula is consumed both orally and through a feeding tube. Since insurance companies typically cover amino acid–based elemental formula if it is administered via a feeding tube, there is an economic incentive to use a feeding tube in order to maintain insurance coverage for the formula. AB 163 would eliminate the financial incentive to use a feeding tube over oral consumption. Other important barriers to oral consumption remain, particularly the taste of the formula, which is too offensive for many to consume in sufficient amounts. As a result, while a shift toward increased orally administered formula could occur over time, CHBRP has no basis for estimating that the use of amino acid–based elemental formula via feeding tube would decrease in the short term. However, by eliminating the financial incentive to opt for a feeding tube over oral consumption, AB 163 could potentially result in long-term benefits of increasing the proportion of people using amino acid–based elemental formula through oral consumption. Health benefits of oral consumption versus feeding tube would include improved oral feeding skills among young children and reduced complications from feeding tubes (Schauster and Dwyer, 1996; Schrag et al., 2007).

### **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 EGID. 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; Pasha et al., 2007; Straumann and Simon, 2005; Vanderheyden et al., 2007).

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).

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<sup>16</sup> See Table 1. It is estimated that 612 persons with EGID using oral formula would gain coverage for amino acid–based elemental formula and three persons with EGID using feeding tubes would gain coverage for formula.

Since AB 163 is not anticipated to affect utilization of amino acid–based elemental formula, AB 163 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 163 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 but not increased survival or decreased mortality. As such, AB 163 is not expected to result in a reduction in premature death.

Little research was identified detailing the economic costs associated with EGID. One study of 30 adults found that one person was required to change professions due to his EE (Straumann et al., 2003). In spite of the lack of research in this area, it is reasonable to assume that there are economic costs attributed to EGID, where persons with EGID and parents of those with EGID are absent from work and school due to lost time associated with diagnosing the illness and seeking treatment. The utilization of amino acid–based elemental formula may help ameliorate some economic costs by controlling symptoms. However, since AB 163 is not expected to increase overall utilization of amino acid–based elemental formula, it is not expected to reduce the economic costs associated with EGID.

## APPENDICES

### Appendix A: Text of Bill Analyzed

INTRODUCED BY Assembly Member Emmerson

January 27, 2009

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 163, as introduced, Emmerson. Amino acid-based elemental formulas.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and 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 acid-based elemental formulas, regardless of the delivery method, for the diagnosis and treatment of eosinophilic gastrointestinal disorders, as defined, when the prescribing physician has issued a written order stating that the amino acid-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. (a) Every health care service plan contract, except a specialized health care service plan contract, that is issued, amended, or renewed on or after January 1, 2010, that provides coverage for hospital, medical, or surgical expenses shall provide coverage for the use of amino acid-based elemental formulas, regardless of the delivery method, for the diagnosis and treatment of eosinophilic gastrointestinal disorders when the prescribing physician has issued a written order stating that the amino acid-based elemental formula is medically necessary.

(b) For purposes of this section, "eosinophilic gastrointestinal disorders" means disorders that are characterized by having above normal amounts of eosinophils, a type of white blood cell, in the digestive system.

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

10123.197. (a) Every health insurance policy issued, amended, or renewed on or after January 1, 2010, that provides coverage for hospital, medical, or surgical expenses shall provide coverage for the use of amino acid-based elemental formulas, regardless of the delivery method, for the diagnosis and treatment of eosinophilic gastrointestinal disorders when the prescribing physician has issued a written order stating that the amino acid-based elemental formula is medically necessary.

(b) For purposes of this section, "eosinophilic gastrointestinal disorders" means disorders that are characterized by having above normal amounts of eosinophils, a type of white blood cell, in the digestive system.

(c) 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 163, a bill that would require specified health care service plan contracts and health insurance policies to provide coverage for amino acid–based elemental formula for the diagnosis and treatment of EGID.

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 EGID. Due to the rarity of EGID 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 assessed the effectiveness of amino acid–based elemental formula for the treatment of EGID. The literature search also specified retrieval of journal articles that addressed the use of biologic therapeutics to treat EGID, a new form of treatment for these disorders on which clinical trials are underway.

For all topics, the literature search was limited to effectiveness studies published in English. The literature reviewed includes studies on the use of formula to treat EE that were discussed in CHBRP’s report on AB 2174, a similar bill introduced in 2008, as well as additional studies published since CHBRP issued that report.

The following databases that index peer-reviewed literature were searched: PubMed (MEDLINE); Business Sources Complete; Cochrane Library<sup>17</sup>; EconLit; Web of Science<sup>18</sup>; and Cumulative Index of Nursing and Allied Health Literature (CINAHL).

Web sites maintained by the following organizations that publish systematic reviews and evidence-based guidelines were searched: National Guideline Clearinghouse (NGC); International Network of Agencies for Health Technology Assessment (INAHTA); National Institute for Clinical Excellence (NICE); NHS Centre for Reviews and Dissemination; Scottish Intercollegiate Guideline Network (SIGN); Agency for Healthcare Research and Quality (AHRQ); National Institutes of Health (NIH) (including the National Institute of Diabetes, Digestive and Kidney Diseases); Institute for Clinical Systems Improvement (ICSI); World Health Organization (WHO)

The literature search yielded a total of 93 abstracts regarding the effectiveness of amino acid–based elemental formula for the treatment of EGID. 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.

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<sup>17</sup> Encompasses the following databases: Cochrane Register of Controlled Clinical Trials, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment Database, and NHS Economic Evaluation Database.

<sup>18</sup> Includes the Science Citation Index Expanded and the Social Science Citation Index.



EE and EG were the only EGID for which literature on the effectiveness of amino acid–based elemental formula was retrieved. Eleven studies met the inclusion criteria and were included in the medical effectiveness review. Five of these were empirical studies of the medical effectiveness of elemental formula for the treatment of these disorders and six were review articles that contained pertinent background information.

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). The single article on EG discussed a case report of an 11-year-old patient on elemental formula treatment.

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 (RCTs) 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 163:

amino acid  
amino acid-based  
amino acid-based formulas  
elemental diet(s)  
elemental formula(s)(ae)  
hypoallergenic formula(s)

E028\*  
Elecare  
Neocate  
Nutramigen  
Tolerex  
Vivonex

biologic(s)  
mepolizumab  
TRFK-5  
monoclonal anti-IL-5 antibody(ies)  
anti-IL-5  
anti-IL-5 antibody(ies)  
anti-eosinophil agent(s)  
antibodies against interleukin 5  
biologic molecule(s)

eosinophilia  
eosinophilic  
eosinophilic colitis  
eosinophilic duodenitis  
eosinophilic enteritis  
eosinophilic esophagitis  
eosinophilic gastritis  
eosinophilic gastroenteritis  
eosinophil(s)

EGID  
eosinophilic GI disease  
eosinophilic Gastrointestinal disease

\* 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 to treat EGID analyzed by the medical effectiveness team. Tables C-1a and C-1b 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-2a and C-2b summarize findings from the studies reviewed. These tables include studies that were reviewed for the report CHBRP issued on AB 2174, a similar bill introduced in 2008, and one new study added for the medical effectiveness review for AB 163, indicated in bold in the tables below.

**Table C-1a.** 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 | 1 nonrandomized study with comparison groups | 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 <sup>19</sup> and co-diagnosed with eosinophilic esophagitis | U.S. (Baltimore)    |
| Liacouras et al., 2005  | 1 nonrandomized study with comparison groups | 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) |

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

| Citation            | Type of Study Design | Intervention                       | Population Studied   | Location          |
|---------------------|----------------------|------------------------------------|----------------------|-------------------|
| Cehade et al., 2007 | Case Report          | Amino acid–based elemental formula | 1 11-year-old female | U.S. (N.Y., N.Y.) |

<sup>19</sup> Gastroesophageal reflux disease

**Table C-2a.** 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)<br><br>Improvement of esophageal histology (number of eosinophils visible upon biopsy) | 1 nonrandomized study with a comparison group | <ul style="list-style-type: none"> <li>Statistically significant</li> </ul> | Better              | <ul style="list-style-type: none"> <li><b>Elemental formula</b><br/>After treatment with elemental formula, 15/25 children resolved vomiting, 4/25 resolved abdominal pain, 2/25 children resolved dysphagia<br/><br/>Peak eosinophil counts<sup>20</sup> for children treated with elemental formula: pre-treatment <math>58.8 \pm 31.9</math>; post-treatment <math>3.6 \pm 6.5</math></li> <li><b>Food elimination diet</b><br/>After treatment with 6-food elimination diet, 15/35 children resolved vomiting, 8/35 resolved abdominal pain, 8/35 children resolved dysphagia<br/><br/>Peak eosinophil counts<sup>7</sup> for children treated with 6-food elimination diet: pre-treatment <math>80.2 \pm 44.0</math>; post-treatment <math>13.6 \pm 23.8</math></li> </ul> | <ul style="list-style-type: none"> <li>Somewhat generalizable: U.S. population, small sample size (n=60)</li> </ul> | <ul style="list-style-type: none"> <li>Evidence from a nonrandomized study suggests that treatment with 6-food elimination diet or elemental formula improves clinical symptoms and esophageal histology</li> </ul> |

<sup>20</sup>  $\leq 10$  eosinophil/high-power field (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-2a.** 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  |
|--|-----------------|---|--|---|---|---|
| <p>Resolution of symptoms (poor weight gain, diarrhea, food refusal, mucous emesis, abdominal pain)</p> <p>Improvement of esophageal histology (number of eosinophils visible upon biopsy)</p> | 1 case series   | <ul style="list-style-type: none"> <li>Statistically significant</li> </ul> | <ul style="list-style-type: none"> <li>Better</li> </ul> | <ul style="list-style-type: none"> <li>Resolution of symptoms: n=8/10</li> <li>Improvement of symptoms: n=2/10</li> <li><i>Pre-formula</i>: maximal esophageal eosinophil count: median # of esophageal eosinophils/HPF: 41 (range: 15-100)</li> <li><i>Post-formula</i>: maximal esophageal eosinophil count: median # of esophageal eosinophils/HPF: 0.5 (range: 0-22)</li> </ul> | <ul style="list-style-type: none"> <li>Somewhat generalizable: U.S. population, small sample size (n=10)</li> </ul> | <ul style="list-style-type: none"> <li>Evidence from one case series suggests that treatment of eosinophilic esophagitis with elemental formula is effective and resolves clinical symptoms and esophageal histology</li> </ul> |

**Table C-2a.** 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  |
|---|---|---|--|---|---|---|
| <p>Resolution of symptoms (GER<sup>21</sup> symptoms, dysphagia)</p> <p>Improvement of esophageal histology (number of eosinophils visible upon biopsy)</p> | 1 nonrandomized study with a comparison group | <ul style="list-style-type: none"> <li>Statistically significant</li> </ul> | <ul style="list-style-type: none"> <li>Better</li> </ul> | <ul style="list-style-type: none"> <li><b>Elemental formula</b><br/> <i>Pre-formula:</i><br/> # with GER symptoms: 134/160<br/> # with dysphagia: 30/160<br/> average # of esophageal eosinophils/HPF: <math>38.7 \pm 10.3</math><br/><br/> <i>Post-formula:</i><br/> # with GER symptoms: 3/160<br/> # with dysphagia: 1/160<br/> average # of esophageal eosinophils/HPF: <math>1.1 \pm 0.6</math></li> <li><b>Food elimination diet</b><br/> <i>Pre-diet:</i><br/> # with GER symptoms: 54/75<br/> # with dysphagia: 21/75<br/> average # of esophageal eosinophils/HPF: <math>47.5 \pm 12.1</math><br/><br/> <i>Post-diet:</i><br/> # with GER symptoms: 2/75<br/> # with dysphagia: 1/75<br/> average # of esophageal eosinophils/HPF: <math>5.3 \pm 2.7</math></li> </ul> | <ul style="list-style-type: none"> <li>Generalizable: U.S. population (sample size: n=160)</li> </ul> | <ul style="list-style-type: none"> <li>Evidence from a nonrandomized study suggests that strict use of elemental formula is effective and resolves clinical symptoms and esophageal histology</li> <li>Evidence from a nonrandomized study suggests that food elimination diet improves clinical symptoms and esophageal histology</li> </ul> |

<sup>21</sup> GER = gastroesophageal reflux

**Table C-2a.** 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   |
|---|-----------------|---|--|--|---|--|
| <p>Resolution of symptoms (vomiting, abdominal pain, heartburn, water brash, globus, dysphagia, chest pain, night cough, irritability)</p> <p>Improvement of esophageal histology (number of eosinophils visible upon biopsy)</p> | 1 case series   | <ul style="list-style-type: none"> <li>Statistically significant</li> </ul> | <ul style="list-style-type: none"> <li>Better</li> </ul> | <p><i>Pre-formula:</i></p> <p># with abdominal pain: 40<br/>           # with vomiting: 36<br/>           # with heartburn: 27<br/>           # with water brash: 11<br/>           # with globus: 9<br/>           # with dysphagia: 7<br/>           # with chest pain: 4<br/>           # with night cough: 5<br/>           # with irritability: 3<br/>           median # of esophageal eosinophils/HPF: <math>33.7 \pm 10.3</math></p> <p><i>Post-formula:</i></p> <p># with abdominal pain: 2<br/>           # with vomiting: 1<br/>           # with heartburn: 2<br/>           # with water brash: 1<br/>           # with globus: 1<br/>           # with dysphagia: 0<br/>           # with chest pain: 0<br/>           # with night cough: 1<br/>           # with irritability: 0<br/>           median # of esophageal eosinophils/HPF: <math>1.0 \pm 0.6</math></p> | <ul style="list-style-type: none"> <li>Somewhat generalizable: U.S. population, small sample size (n=51)</li> </ul> | <ul style="list-style-type: none"> <li>Evidence from one case series suggests that elemental formula significantly improves both clinical symptoms and histological evidence of disease in children and adolescents with eosinophilic esophagitis</li> </ul> |



**Table C-2b.** Summary of Findings from Studies of the Effectiveness of Amino Acid–Based Elemental Formula for Diagnosis and Treatment of Eosinophilic Gastroenteritis

| Outcome  | Research Design    | Statistical Significance   | Direction of Effect                                      | Size of Effect  | Generalizability  | Conclusion  |
|--|--------------------|--|--|---|---|---|
| <p>Resolution of symptoms (gastric and proximal small intestinal mucosal disease)</p> <p>Improvement of gastritis histology (number of eosinophils visible upon endoscopy)</p> | <p>Case report</p> | <ul style="list-style-type: none"> <li>No formal test of statistical significance</li> </ul> | <ul style="list-style-type: none"> <li>Better</li> </ul> | <ul style="list-style-type: none"> <li>After 9 weeks of dietary therapy with an amino acid–based formula, the patient’s severe gastrointestinal mucosal ulcers and pseudopolyps (found upon endoscopy) resolved almost completely</li> <li>Histologically, the patient’s gastritis improved, with a maximum of 10 eosinophils per HPF</li> <li>The patient’s swallowing and chewing normalized, and she had no gastrointestinal symptoms and no recurrence of her disease after 9 weeks of dietary therapy</li> </ul> | <ul style="list-style-type: none"> <li>Limited because only enrolled one subject</li> </ul> | <p>Findings from one case report suggests that elemental formula significantly improves histological abnormalities of gastric and proximal small intestinal mucosal disease</p> |

## 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 [www.chbrp.org/costimpact.html](http://www.chbrp.org/costimpact.html).

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 that provides data and analyses per the provisions of CHBRP's 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 (2007) 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 approximately 53,000 households. More information on CHIS is available at [www.chis.ucla.edu/](http://www.chis.ucla.edu/)
2. The latest (2008) 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] and Point of Service Plans [POS]),
  - premiums for policies regulated by the California Department of Insurance (CDI) (primarily preferred provider organizations [PPOs] and fee-for-service plans [FFS]), and
  - premiums for high deductible health plans (HDHPs) for the California population covered under employment-based health insurance.

This annual survey is currently 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](http://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-](http://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 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 (2008 Group Health Insurance Survey) contains data from seven major California health plans regarding their 2007 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 96% of the privately insured market: 98% of privately insured enrollees in full-service health plans regulated by DMHC and 82% of lives privately insured health insurance products regulated by CDI.

#### *Public 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—comprise 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](http://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 online at <http://www.dhcs.ca.gov/dataandstats/statistics/Pages/BeneficiaryDataFiles.aspx>.

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 Managed 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-MRMIP 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/](http://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 products subject to state-mandated health insurance benefits.
- Cost impacts are only for the first year after enactment of the proposed mandate
- 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 [www.chbrp.org/documents/longterm\\_impacts\\_final011007.pdf](http://www.chbrp.org/documents/longterm_impacts_final011007.pdf)
- Several recent studies have examined the effect of private insurance premium increases on the number of uninsured (Chernew, et al., 2005; 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% increase in premiums (about -0.088), divided by the average percentage of insured individuals (about 80%), multiplied by 100%, i.e.,  $\{[-0.088/80] \times 100\} = -0.11$ ). 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: [www.chbrp.org/documents/uninsured\\_020707.pdf](http://www.chbrp.org/documents/uninsured_020707.pdf).

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 post-mandate 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 EGID are obtained from a number of published data sources. Unique, specific diagnostic codes for EGID were only introduced this year, and thus were not yet on MarketScan and could not be used to estimate prevalence. CHBRP did, however, use a collection of ICD-9 diagnostic codes suggested by the content expert (see below) that are often used for coding EGID diagnoses, but CHBRP believes that results from this data pull greatly overstate actual prevalence and therefore should not be relied upon. CHBRP thus relied on literature and content experts to determine prevalence rates for the model assumptions shown above. The ICD-9 codes used in the MarketScan data extract are as follows, and include some codes that had been used in the 2008 data extract as well as some new ones for this year:

#### **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

#### **Additional codes used for 2009 analysis:**

530.1 Esophagitis, nonspecific  
530.1 Colitis, noninfectious

#### **New, EGID specific codes**

530.13 Eosinophilic Esophagitis  
535.7 Eosinophilic Gastritis  
558.41 Eosinophilic Gastroenteritis  
558.42 Eosinophilic Colitis

Of those diagnosed with EGID, a proportion is assumed to use the elemental formulas addressed by this bill. For the 2008 analysis (AB 2174), this percentage was assumed to be 25%, based on published estimates that 74% to 77% of children experienced improvement from an elimination diet, and therefore CHBRP assumed that 25% would need to take—or benefit from taking—the elemental formula. For this year’s analysis, CHBRP incorporated additional information from both the literature and expert opinion suggesting that due to poor palatability and lifestyle considerations, the percentage who actually consume formula would be less than the full 25% who *could* actually benefit from it. The one exception would be infants, where it could be reasonably assumed 100% of infants would need the formula and would accept it due to lack of prior established taste preferences. While the estimates of the percentage using formula vary widely from center to center, all were below 25% and ranged from 1% to 15% using it as part to 100% of patients’ diets (part-to-full-time). CHBRP used data derived from an unpublished analysis done at the Cincinnati Center for Eosinophilic Disorders (Cincinnati Children’s Hospital Medical Center), finding that 12% to 15% of individuals with EGID used formula full-

time over the course of a year. Based on input from content experts, this is an upper bound, conservative estimate of consumption.

Of children and teens on formula, some consume it as 100% of their diet, some as a partial percent, and some take it orally while others take it via feeding tube. For last year's analysis, CHBRP assumed that all consumption was at 100%, and the percentage assumed to be using feeding tubes had been identified using CPT (Current Procedural Terminology) and HCPCS (Healthcare Common Procedure Coding System) codes. For this 2009 analysis, however, CHBRP again used data from the Cincinnati analysis and assumed that of those on formula full-time (15% of people with EGID), 40% (6% of people with EGID) receive the formula via tube, and the remaining 60% (9% of those with EGID) take it orally full-time. CHBRP also assumed that 10% of children and teens with EGID consume formula part time—based on the 25% who could benefit from it, minus the 15% who consume it full-time at 50% of daily calories. Due to lack of available data on the distribution of tube-versus-oral delivery for part-time formula users, CHBRP assumed that all such users consumed it orally.

Among adults, dietary therapy (including elimination diets and elemental formula) has not been evaluated, according to this review of the literature. Instead, studies and current practice in adults have focused on other treatments including acid suppression, dilatation, and corticosteroids. So CHBRP believes it is reasonable to lower these utilization assumptions for adults to half of the estimates for children, such that 7.5% of adults may need to take elemental formula full-time (3% via tube and 4.5% orally), and 5% use it part-time.

## **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:

*The American Partnership for Eosinophilic Disorders submitted information regarding the utilization assumptions used in the cost model to project premium impacts.*

This information is available upon request.

For information on the processes for submitting information to CHBRP for review and consideration please visit [www.chbrp.org/requests.html](http://www.chbrp.org/requests.html).



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## California Health Benefits Review Program Committees and Staff

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

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

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance and thoughtful critiques provided by the members of the National Advisory Council. However, the Council does not necessarily approve or disapprove of or endorse this report. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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