

HB 2103

Social and Financial Impact



- A. The extent to which the treatment or service is generally utilized by a significant portion of the population;
  - House Bill No. 2103 mandates coverage for amino acid-based elemental formula for the diagnosis or treatment of food protein-induced enterocolitis syndrome (FPIES), eosinophilic disorders or short bowel syndrome (SBS).

	# of People Affected	% of Under Age 65 US Population*
Food Protein-Induced Enterocolitis Syndrome (FPIES)	270	0.0001%
Eosinophilic Esophagitis (EoE)	137,873	0.05%
Eosinophilic Gastroenteritis (EGE) and Eosinophilic Gastritis (EG)	78,785	0.03%
Short Bowel Syndrome (SBS)	827	0.0003%
TOTAL	217,756	0.08%

<sup>\*</sup> Assuming US Population =  $325,365,189^1$  with 84.75% of the population being under age  $65^2$ . Under 65 US Population =  $325,365,189 \times 84.75\% = 275,746,998$ 

 According to the report from California, about 4.8% of people with these diseases in California use amino acid-based formula<sup>3</sup>.

# of People Affected	Formula Utilization Rate for Affected People	# of Affected People Using Formula	% of Under Age 65 US Population
217,756	4.8%	10,433	0.004%

Thus, a very small portion of the population utilizes the treatments covered by the bill.

## B. The extent to which such insurance coverage is already generally available;

- The Children's Milk Allergy and Gastrointestinal Coalition U.S. (MAGIC) declares that twenty states in the US have "elemental formula coverage" <sup>4</sup>. However, some of these states do not cover all of the treatments listed in House Bill No. 2103.
- The California report states:
  - "Health plans and insurers cover amino acid—based elemental formulas when administered by a feeding tube. These formulas are not typically covered when taken orally" <sup>3</sup>.
- Although some states provide coverage for the treatments listed in the House Bill No. 2103, it seems more common to cover treatment via feeding tube than treatment via oral formula.

- C. If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatment;
  - According to the report from Virginia, "amino acid-based formulas are widely available for purchase; however, the cost may be prohibitive for individuals and families in some cases" 5.
  - The Virginia report goes on to say:
    - "According to medical experts, for certain conditions, such as GI disorders involving small intestinal failure, the consequences [of not taking the amino acid-based elemental formula] are more severe, and individuals likely obtain the formulas without coverage. Anecdotally, some parents have reported having a feeding tube inserted in their child to obtain coverage because their health insurance covered enteral consumption of elemental formulas, but not oral consumption" 5.
  - Amino acid-based elemental formulas are not the only form of treatment for these conditions. In fact, the report from Virginia states that amino acid-based formulas are only considered standard treatment when treating children with eosinophilic esophagitis<sup>5</sup>.



	Child		Adult	
Condition	Standard Treatment	Alternative Treatment	Standard Treatment	Alternative Treatment
Food Protein-Induced Enterocolitis Syndrome	Х	✓	X	Х
Eosinophilic Esophagitis	✓	✓	X	X
Eosinophilic Gastroenteritis	Х	✓	X	Х
Short Bowel Syndrome	X	✓	X	X

#### The Virginia report explains:

"Extensively hydrolyzed formulas are the first choice for children with food protein-induced enterocolitis syndrome, and amino acid-based elemental formulas are used for children with severe cases who are not able to tolerate the hydrolyzed formulas" 5.



- "Extensively hydrolyzed formulas are the first choice for children with short bowel syndrome, and amino acid-based elemental formulas are recommended for severe cases" 5.
- "Amino acid-based elemental formulas are a primary treatment for children with eosinophilic esophagitis..., but not for adults with the conditions" <sup>5</sup>.
- Although treatment is expensive, elemental formula is not the only, and usually not even the preferred, treatment for the conditions listed in House Bill No. 2103.



- D. If the coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment;
  - According to the report in Virginia written in 2008:
    - "Most health insurance companies do not provide coverage of the formulas. This may be a financial hardship because the formulas' cost could range from three to ten percent of median household income in 2008" 5.



Within the Virginia report, one table, shown below, suggests the cost of elemental formula is more than twice the cost of standard baby formula<sup>5</sup>.

Table 4: Sample Formula Cost for a Five-Month-Old With a Hypersensitivity Disorder Requiring Amino Acid-Based Elemental Formula Versus an Infant Using Standard Baby Formula

	Elemental Formula <sup>a</sup>	Baby Formula <sup>b</sup>
Price per can	\$31.5	\$14.17
Reconstituted ounces per		
can	96 oz	96 oz
Feeding guideline, ounces per day / ounces per month	25-48 / 750-1440 oz	25-48 / 750-1440 oz
Number of cans per month	8-15	8 -15
Estimated monthly cost	\$252-473	\$113-213
Estimated annual cost	\$3,024-5,676	\$1,356-2,556

<sup>&</sup>lt;sup>a</sup> EleCare unflavored powder, at the manufacturer's price of \$189 per case of six.

Note: Feeding guidelines for infants with GI and hypersensitivity conditions on elemental formula vary, and the amount is determined by the physician. In the absence of a standard guideline for these infants, the healthy infant guideline is used. However, the quantity of formula consumed by an infant with GI and hypersensitivity conditions is sometimes greater due to vomiting and diarrhea.

Source: Virginia Department of Health, Women, Infant, and Children program; Ross Laboratories; www.EleCare.com.



b Similac Advance, at the manufacturer's price of \$85 per case of six.

- Similarly, California's 2008 report "estimates an average annual cost of \$11,500 per patient for the amino acid based elemental formulas" 3.
- As explained previously, other treatments are available, and typically more standardly recommended, for people with these conditions. However, "for certain severe cases of these conditions, elemental formulas may be the only treatment for children, when other formulas have failed" 5. In this case, the family may have no choice but to pay out-of-pocket for the treatment if they want to help their child.
- Dependent upon the severity of the condition, it may be critical for patients to take elemental formula, in which case, the costs would be a significant financial burden to most households



# E. The level of public demand for the treatment or service;

• Given the small percentage of people in the US with these conditions and even smaller percentage of these people that seek the treatments, the level of public demand for the treatments is, presumably, low.



- F. The level of public demand for individual or group insurance coverage of the treatment or service;
  - Due to the relatively small percentage of people that need treatment, the general public demand for coverage is low. However, due to the high costs of treatment, the demand within the population of people that need the treatment is presumably very high.



- G. The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts;
  - Neither the Virginia nor California report listed evidence of a collective bargaining organization negotiating for this coverage.
  - According to the Virginia report:
    - "Labor unions do not appear to have advocated specifically for the inclusion of this benefit in their health benefit packages. Typically, labor unions advocate for broader benefits, rather than a benefit as specific as the proposed mandate" 5.



- The California report is nearly identical to the Virginia report on this matter:
  - o "Based on conversations with the largest collective bargaining agents in California, CHBRP [California Health Benefits Review Program] 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>3</sup>.
- It appears the level of interest of labor unions in negotiating privately for inclusion of this coverage in group contracts is minimal.



- H. The impact of indirect costs which are costs other than premiums and administrative costs, on the question of the costs and benefits of coverage.
  - There are no significant indirect costs associated with providing the coverage detailed in House Bill No. 2103.
    - Virginia's report lists at least one concern with this type of mandate:
    - "For certain conditions, amino acid-based formulas are recommended as an alternative formula or treatment, and for other conditions their use is not standard medical practice. Mandating their coverage could promote the utilization of ineffective treatment as opposed to the most effective or recommended treatment" 5.



- As the Virginia report points out, there is a possibility for long-term savings, due to the prevention of conditions worsening, if benefits are covered.
  - "Mandated coverage of amino acid-based formulas used to treat severe GI and hypersensitivity conditions may reduce the total cost of health care. Left untreated, certain severe GI and hypersensitivity conditions may result in increased long-term costs resulting from adverse health consequences" 5.
- Conversely, the California report suggests that although there are costs associated with people having these conditions, a mandate like House Bill 2103 will not decrease these costs because the mandate does not affect utilization rates<sup>3</sup>.



- o "In spite of the lack of research in this area, it is reasonable to assume that there are substantial economic costs attributed to eosinophilic disorders and SBS, where persons and parents are absent from work and school due to lost time associated with illness and seeking treatment. The utilization of amino acid-based elemental formula may help ameliorate those costs by controlling symptoms. However, since AB 2174 is not expected to increase overall utilization of amino acidbased elemental formula, it is not expected to reduce the economic costs associated with eosinophilic disorders and SBS" 3.
- Overall, the indirect costs of this mandate are very minimal.



- A. The extent to which insurance coverage of the kind proposed would increase or decrease the cost of the treatment or service;
  - When describing the financial impact of similar mandates that were proposed in Virginia in 2008, the Virginia report explained:
    - "The potential impact of the proposed mandates on the cost of amino acid-based formulas is unknown, but no increase is expected"<sup>5</sup>.
    - For severe cases of these conditions, "establishing a mandate largely will likely only change the payer... because individuals face dire adverse consequences in the absence of use" 5.



- Within the California report, the CHBRP stated it did not expect "any changes to the per-unit cost of these products due to" the proposed mandate in California, focusing on EE and SBS<sup>3</sup>.
- The mandated coverage would not significantly change the cost of treatment, it would only change who is paying for the treatment – the employer not the member.



## B. The extent to which the proposed coverage might increase the use of the treatment or service;

- California's report claims there would be no significant change in utilization:
  - "The utilization of amino acid—based elemental formula taken administered by feeding tube or ingested orally is estimated to remain essentially unchanged under... [California's proposed mandate]"3
  - "The utilization of formula among those with SBS or eosinophilic disorders who have a feeding tube would remain unchanged.... [The] feeding tube would remain in place to maintain coverage by health plans and insurers and because poor palatability lowered patient compliance requiring frequent enteral feeding for those on a strict amino acid-based formula diet" 3.



- "CHBRP also estimates no change in... utilization rates post mandate for the elemental formula for persons with eosinophilic disorders....Those with eosinophilic disorders who needed the oral formula for sufficient nutrition would have purchased it regardless of insurance coverage. For those with severe conditions, the medical necessity would outweigh cost concerns" 3.
- Conversely, Virginia's report seems to suggest that the utilization rate could increase:
  - "Mandating coverage could increase the number of individuals that have access to amino acid-based formulas covered by private insurance, thereby perhaps increasing the utilization rate when prescribed or ordered as a course of treatment" <sup>5</sup>.



- "In some cases, families who could not afford the recommended level of amino acid-based formulas may increase their utilization as a result of the [mandate]" 5.
- One concern... is that amino acid-based formulas would be prescribed or ordered by physicians for GI and hypersensitivity disorders for which they are not standard medical treatment. If this were to occur, the utilization rate may increase proportionately to the over-prescribing of the formulas" 5.
- Although there is a mix of speculations on whether or not the utilization rate of treatment would increase, this should be of no concern since the total number of people with these conditions is so small. Even if all of the members with these conditions sought treatment, they would still make up a very small percentage of the overall membership population.



- C. The extent to which the mandated treatment or service might serve as an alternative for more expensive treatment or service;
  - As explained in the Virginia report:
    - "The alternative to amino acid-based elemental formulas is other types of formulas, steroids, or surgery for certain GI and hypersensitivity conditions. Families and Children's MAGIC also report anecdotally that mandating coverage would allow some children to consume elemental formulas orally rather than through a feeding tube" 5.



 Covering elemental formula claims would be less expensive than covering claims for surgery, and covering claims for orally consumed elemental formula would be less expensive than covering claims for feeding tube insertion and care.



- D. The extent to which insurance coverage of the health care service or provider can be reasonably expected to increase or decrease the insurance premium and administrative expenses of policyholders;
  - Based on a 2008 survey of Virginian health insurers, conducted by the Bureau of Insurance, monthly premium estimate for coverage ranges from \$0.05 to \$1.46 5.

Estimated Monthly Premium Impact				
	# of Responses	Median Estimate	Highest Estimate	Lowest Estimate
Group (standard)	15	\$0.40	\$1.46	\$0.05



- However, the Virginia report then comments, "A public health expert consulted for this evaluation stated that the estimates of monthly premium impact appear to be high given the prevalence of the disorders that utilize amino acid-based formulas" 5
  - The Virginia report assumed "the administrative expenses for insurance companies would likely be similar to other mandates" <sup>5</sup>.
  - According to the findings from the California report:
    - "Coverage of amino acid-based elemental formulas for eosinophilic esophagitis and short bowel syndrome are estimated to raise premiums by 0.0147 percent to 0.0181 percent in the group market" <sup>5</sup>.



# E. The impact of this coverage on the total cost of health care.

 Compiling the research from the 2008 Virginia report<sup>5</sup>, 2008 California report<sup>3</sup>, and a 2016 New Jersey report<sup>7</sup>, Segal has calculated reasonable values for the following:

Prevalence		
Average Prevalence of Conditions	0.01%	
# of Kansas Members with Conditions	85	
Usage		
Average Percentage of Affected People Seeking Treatment	22%	
# of Kansas Members with Conditions	85	
# of Affected Kansas Members Seeking Treatment	19	



Average Annual Cost Per User		
Estimated Annual Formula Cost Per User	\$16,000	
Total Annual Cost for Treatment		
# of Affected Kansas Members Seeking Treatment	19	
Average Annual Formula Cost Per User (2017 Kansas)	\$16,000	
Total Annual Cost for Treatment (2017 Kansas)	\$304,000	

Based on these findings, the point estimated total annual cost to cover formula treatment for the listed conditions is \$304,000, close to the original estimate provided for the actuarial note. This estimate includes several assumptions so the actual cost could vary. Regardless, the impact is immaterial to the plan.



#### SOURCES

- 1.) <a href="https://www.census.gov/popclock/">https://www.census.gov/popclock/</a>
- 2.) 1data\_tables.php?component=pyramid
- 3.) <a href="http://www.chbrp.org/documents/ab\_2174\_report.pdf">http://www.chbrp.org/documents/ab\_2174\_report.pdf</a>
- 4.) <a href="http://childrensmagicus.org/coverage-states/">http://childrensmagicus.org/coverage-states/</a>
- 5.) <a href="http://leg2.state.va.us/dls/h&sdocs.nsf/By+Year/RD2662008/\$file/RD266.pdf">http://leg2.state.va.us/dls/h&sdocs.nsf/By+Year/RD2662008/\$file/RD266.pdf</a>
- 6.) <a href="https://www.numbeo.com/cost-of-living/compare\_cities.jsp?country1=United+States&country2=United+States&city1=Topeka%2C+KS&city2=Los+Angeles%2C+CA">https://www.numbeo.com/cost-of-living/compare\_cities.jsp?country1=United+States&country2=United+States&city1=Topeka%2C+KS&city2=Los+Angeles%2C+CA</a>
- 7.) <a href="http://www.njleg.state.nj.us/2016/Bills/A0500/389\_E1.HTM">http://www.njleg.state.nj.us/2016/Bills/A0500/389\_E1.HTM</a>

