

*Information Summary and Recommendations*

# Treatment of Eosinophilia Gastrointestinal Associated Disorders (EGIDs)

## Mandated Benefit Sunrise Review

December 2013



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## **THE SUNRISE REVIEW PROCESS**

The legislature passed House Bill 1191 in 1997. This bill amended the statute on mandated health insurance benefits. The statute now requires proponents of such mandates to provide specific information to the legislature. If the legislature requests a review, the Department of Health makes recommendations on the proposal using statutory criteria. This review is done only at the request of the chairs of legislative committees, usually the House Health Care and Wellness Committee or Senate Health and Long-Term Care Committee.

The criteria for these “sunrise reviews” are contained in RCW 48.47.030. The legislature’s intent is that all mandated benefits show a favorable cost-benefit ratio and do not unreasonably affect the cost and availability of health insurance. RCW 48.47.005 states, “. . .the cost ramifications of expanding health coverage is of continuing concern; and that the merits of a particular mandated benefit must be balanced against a variety of consequences which may go far beyond the immediate impact upon the cost of insurance coverage.”



## **EXECUTIVE SUMMARY**

### **Proposal**

Substitute House Bill (SHB) 1216 (Chapter 168, Laws of 2013), relating to eosinophilia gastrointestinal associated disorders (EGIDs), directed the Department of Health (department) to conduct a sunrise review of the proposal in House Bill (HB) 1216. That bill recommended an amendment to RCWs 48.20.520, 48.21.300, 48.44.440, and 48.60.510, adding coverage of formulas necessary for the treatment of EGIDs, regardless of the delivery method of the formula, to the existing insurance mandate for formulas for treating phenylketonuria (PKU). The proposal would apply to state-regulated individual and group health plans and disability plans.

### **Background**

EGIDs are chronic inflammatory disorders in the gastrointestinal system associated with an increase in eosinophils, a naturally produced type of white blood cell that helps fight infections. Eosinophils may be activated in allergic conditions, including food allergies. When activated, eosinophils release substances capable of damaging tissue. The esophagus, stomach, intestines, or colon can be affected. Clinical symptoms include difficulty swallowing, food becoming stuck in the esophagus, reflux, choking, anemia, malnutrition, difficulty feeding and/or gaining weight, poor growth and weight loss, vomiting, and heartburn.

Pharmacologic treatments such as corticosteroids and, in the case of food allergies, dietary therapies are often used to treat the disorder. Dietary treatment includes targeted elimination diets where foods that test positive during allergy testing or foods with a history of causing a reaction with the individual are removed from the diet. Empiric six-food elimination diets where the six most common allergenic foods are avoided (milk, wheat, soy, peanuts, tree nuts, and fish/shellfish) is also used.

For some patients, their diet is so restrictive that they are unable to meet nutritional needs by food alone, and an amino acid-based formula is needed for nutrition. The cellular components of the immune system can't recognize these proteins, so they don't create an immune response. The majority of elemental formulas are nutritionally complete, providing enough calories and nutrients such as essential fats, amino acids, vitamins and minerals for normal growth.<sup>1</sup>

EGIDs are uncommon, and those with the disorder who require an elemental formula make up an even smaller percentage of the population. Many Washington insurance carriers cover these diets when delivered by feeding tube. Yet, private insurers aren't consistent in their coverage. Many will not cover the cost if the formula is delivered orally. Medicaid covers these products for children under age 21 when fed orally and for all ages when tube fed for specific conditions, including the inability to meet nutrient needs by food alone. Many families have trouble paying out-of-pocket for elemental formulas that can cost up to \$1,200 per month.

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<sup>1</sup> Barry K. Wershil, M.D., "Elemental Diets for Eosinophilic Esophagitis: Theories and Practice," American Partnership for Eosinophilic Disorders (APFED).

## **Recommendation**

The department supports the addition of a mandate to require coverage of amino acid-based elemental formulas to treat EGIDs. The proposal's concept is in the best interest of the public and the benefits outweigh the costs of covering elemental formulas. However, we recommend some changes to the draft legislation to clarify the mandate and address some concerns noted during our review. Some of these include amending the current PKU mandate and ensuring the mandate is for medically necessary, physician-directed elemental formulas. We recommend the following changes to the draft bill:

- Don't amend the language in the PKU statutes, RCW 48.20.520, 48.21.300, 48.44.440 and 48.60.510. Instead, create new subsections under chapters 48.20, 48.21, 48.22, and 48.60 RCW to specifically address EGIDs.
- Include language stating coverage is required for "elemental formulas" or "medical foods."
- Include language that requires the elemental formulas be medically necessary and ordered by a physician or other health care provider with prescriptive authority.



## **SUMMARY OF INFORMATION**

### **Proposal**

Substitute House Bill (SHB) 1216 (Chapter 168, Laws of 2013), relating to eosinophilia gastrointestinal associated disorders (EGIDs), directed the Department of Health (department) to conduct a sunrise review of the proposal set forth in House Bill (HB) 1216. That bill proposed an amendment to add coverage of formulas necessary for the treatment of EGIDs, regardless of the delivery method of the formula, to the existing insurance mandate for coverage of formulas for treating phenylketonuria (PKU). The proposal would apply to state-regulated individual and group health plans and disability plans.

### **Public Participation**

The department shared the proposal with interested parties and began accepting comments in May 2013. We received letters from three parents of children with EGIDs explaining the high cost of these elemental formulas. One said they pay about \$14,000 a year on formulas. All of them said this mandate is necessary, because elemental formulas are the only way their children can receive the basic nutrition they need to survive.

Regence BlueShield recommended that the word “elemental” be added to make the law more specific and prevent confusion.

In addition, we received a letter from Premera Blue Cross, which had following concerns:

- Premera covers medically necessary enteral nutritional support by feeding tube, because this support is predicated on the patient needing a specific medical intervention to obtain nutrition.
- Any state-mandated benefit enacted after Dec. 31, 2011, wouldn't be part of the essential health benefits for 2014 and 2015. The state will have to pay the costs of additional mandates for any subsidies provided under the Affordable Care Act unless the federal law is changed in 2016.
- The proposal requires Premera to cover formulas that are available over the counter. Insurance policies don't generally cover over-the-counter items. Premera expressed concerns that mandating this type of coverage could lead to an increased number of mandates for other types of nutritional or dietary supplements or foods.

A public hearing was held July 22, 2013, in Tumwater, Washington.

Jeff Schwartz, the applicant and parent of a child with an EGID, presented the proposal along with Dr. Uma Pisharody, a pediatric gastroenterologist specialist. They gave an overview of eosinophilic gastrointestinal disorders, diagnosis, and symptoms. They went over the treatment options, which include restrictive diets based on allergy testing, elimination diets (avoiding top allergens), strict use of an elemental formula, and also the use of steroids. They explained elemental formulas and provided some data on usage, as well as costs. They also provided data on incidence rates of EGIDs and those who actually require elemental formulas. Data from the applicant showed the national average of EGIDs at 1:2,000 population compared to Washington

State's 1:5,000. They estimated those acutely ill who would require medical foods at 1:30,000 to 1:75,000 people. They ended their presentation with information on coverage of elemental formulas across the United States, showing 13 states having some sort of coverage and 14 more seeking coverage.

Dr. Pisharody stated that she and her partner at Swedish Medical Center treat a few dozen patients with EGIDs. She described the challenges her patients encounter in getting their insurance to cover oral elemental formulas. She said she never has put in a feeding tube just because oral formula wasn't covered. However, she estimated that she has resorted to using steroids in place of an elemental formula with 90 percent of her patients, because they can't afford to pay for oral formulas without coverage. She doesn't like using steroids unless it's medically necessary due to side effects of long-term use. She also clarified for the panel that she writes prescriptions for oral elemental formula (even though it's not always required by the distributor) and that it's always under a physician's care.

Three mothers of children with EGIDs testified in support of the proposal and gave examples of the high costs of the formula. One mother stated her son's formulas cost \$840 per month. They showed examples of the formula and said that it tastes horrible, adding that no one would willingly consume it without a compelling medical reason.

Following the hearing, there was an additional 14-day comment period for follow-up information. There was a final public comment period following the release of the draft report for interested parties to submit corrections or rebuttals.

## **Background**

### **EGIDs**

EGIDs are chronic, inflammatory disorders in the gastrointestinal system. Eosinophils, a type of white blood cell, act as if food is a harmful foreign substance and attack the gastrointestinal system. Eosinophils circulate in the blood and tissues and are control mechanisms associated with allergies and asthma. When the body wants to attack a substance, such as an allergy-triggering food or airborne allergen, eosinophils respond by moving into the area and releasing a variety of toxins.<sup>2</sup>

When the body produces too many eosinophils, they cause chronic inflammation and even narrowing of the esophagus, which can result in tissue damage and injury to the affected organ. In EGIDs, there are above normal numbers of eosinophils in the digestive system. Symptoms may include difficulty swallowing, food becoming stuck in the esophagus, reflux, choking, anemia, malnutrition, difficulty feeding and/or gaining weight, poor growth and weight loss, vomiting and heartburn. EGIDs are diagnosed according to the location where the levels of eosinophils are elevated, such as:

- Eosinophilic Esophagitis (EoE)

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<sup>2</sup> <http://apfed.org/drupal/drupal/e-learning-center> and Chris a. Liacouras, MD, et al, "Eosinophilic Esophagitis: Updated Consensus Recommendations for Children and Adults," *Journal of Allergy and Clinical Immunology*, July 2011.

- Eosinophilic Gastritis (EG)
- Eosinophilic Gastroenteritis (EGE)
- Eosinophilic Colitis (EC)
- Eosinophilic Enteritis

Many cases of EGIDs occur in association with food allergies. However, in some cases with no obvious cause, it is speculated that the condition is be autoimmune in nature. Although all of these conditions are rare, EOE seems to be the most common, and consequently the most studied.<sup>3</sup>

### **Comparison to Phenylketonuria (PKU)**

In comparison, PKU, for which insurance coverage is already mandated in Washington, is a metabolic disorder that affects the way the body processes protein. Children with PKU cannot use a part of the protein called phenylalanine. If left untreated, phenylalanine builds up in the bloodstream and causes brain damage, severe mental retardation, and other problems of the nervous system.

PKU is one of 29 conditions tested through the newborn screening program. About one in 15,000 babies in Washington State is born with PKU. PKU is treated through a special formula that provides protein and essential nutrients, but little or no phenylalanine. Children born with PKU must continue on amino acid-based metabolic formula for their entire lives.

We received comments during our review that it is not appropriate to place this proposed mandate in the same sections of Title 48 RCW with the mandate for PKU. The reasons for this objection were that EGIDs are not inborn errors of metabolism, dietary management is different, these conditions are less likely to be lifelong, and there are a variety of treatment options for EGIDs.

### **Treatment Options**

#### Pharmacologic Treatments

- Pharmacologic treatments such as corticosteroids have shown to reduce eosinophils or inflammation in patients with EoE. There are other pharmacologic treatments as well, but all seem to result in recurrence of symptoms after stopping the treatment. Systemic corticosteroids can be used for emergency cases, but because of the potential for significant toxicity, they are not recommended for long-term use. Topical corticosteroids can be effective; however, steroid resistance has been seen.<sup>4</sup> Symptoms have also been shown to worsen upon discontinuing steroid therapies.<sup>5</sup>

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<sup>3</sup> Zuo, Li, M.D. and Rothenberg, Marc W., M.D., Ph.D., "Gastrointestinal Eosinophilia," <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2034402/>, accessed June 11, 2013.

<sup>4</sup> Chris A. Liacouras, MD, et al., "Eosinophilic Esophagitis: Updated Consensus Recommendations for Children and Adults," *Clinical Reviews in Allergy and Immunology*, page 13.

<sup>5</sup> Chris A. Liacouras, et al., "Eosinophilic Esophagitis: A 10 Year Experience in 381 Children," *Clinical Gastroenterology and Hepatology*, 2005; 3:1198-1206.

Long-term use of corticosteroids involves the risk of significant side-effects such as cataracts, high blood pressure, and increased risk of infections.<sup>6</sup>

## Dietary Therapy

- Targeted Elimination Diets

In this treatment, foods that test positive during allergy testing or history are removed from the diet. Many patients see their symptoms improve, and this may be their only necessary treatment.

- Empiric Six-Food Elimination Diet

This elimination diet has shown success in some patients. Rather than having allergy tests done, patients eliminate six common allergenic foods (milk, wheat, soy, peanuts, tree nuts, and fish/shellfish). These foods must be restricted in all forms and in any amount.

- Elemental Formula Diet

In this diet, all sources of protein are removed from a patient's diet. An elemental diet includes only an amino acid formula with no whole or partial proteins. Complete resolution is generally achieved with an amino acid-based elemental diet. Only a small subset of children with EGIDs must depend solely on an elemental diet. These are the children who are highly allergic and whose diets are so limited they cannot meet their nutritional needs for normal growth. This treatment is not always successful in older children due to non-compliance.

## Elemental Formula

An elemental diet requires the use of a nutritionally balanced, complete formula to replace or supplement solid food. Since individuals who require an elemental diet cannot get their nutrition through a regular diet, elemental formulas use individual amino acids as the protein source. The cellular components of the immune system cannot recognize these proteins, so they do not create an immune response. The majority of elemental formulas are nutritionally complete, providing adequate amounts calories and nutrients such as essential fats, amino acids, vitamins and minerals for normal growth.<sup>7</sup>

A team approach is often used when starting a child on an elemental diet. Team members may include a gastroenterologist, allergist, social worker, and a registered dietitian (RD). The RD provides nutritional assessment at the beginning of treatment to estimate the caloric intake needed to maintain adequate growth. The RD can also advise on which formula choices are available and appropriate for the patient and can be very helpful if the patient gets to a phase of food reintroduction.

When food allergy is the suspected cause, an elemental diet removes all potential food antigens from the diet and supports nutrition through hypoallergenic formula. Elemental formulas are classified by the FDA as medical foods rather than pharmaceuticals. This is due, in part, to the

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<sup>6</sup> Mayo Clinic Web, <http://www.mayoclinic.com/health/steroids/HQ01431>, accessed August 29, 2013.

<sup>7</sup> Barry K. Wershil, M.D., "Elemental Diets for Eosinophilic Esophagitis: Theories and Practice," APFED.

prohibitive cost of clinical trials in a small population.<sup>8</sup> Medical foods are specially formulated and processed products for the partial or exclusive feeding of patients. The FDA defines medical foods in section 5(b) of the Orphan Drug Act as “a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the dietary management of a specific disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”<sup>9</sup>

Medical foods are distinguished from the broader category of foods for special dietary use by requiring them to be used under medical supervision. They are specially formulated and processed for the patient who is seriously ill or who requires the product as a major treatment modality.

According to the applicant, not all individuals diagnosed with EGIDs will need elemental formulas. Only the most severe cases, where sufficient food cannot be tolerated for normal growth, will require this treatment. Sometimes, elemental formulas are only needed for a brief period of time to stabilize the GI system. Only the most acutely ill may require these formulas for extended periods of time. A majority of children are on elemental formulas for two years or less, until a sufficient number of safe foods can be identified through food trials to meet their nutritional needs.<sup>10</sup> Parents of children on these formulas have stated they are barely palatable, so they wouldn't subject their children to these formulas unless medically necessary.

Elemental formulas can be purchased through a pharmacy, durable medical equipment (DME) provider, or directly from manufacturers such as Abbott Nutrition. In researching the cost of these formulas, such as Elecare and Neocate, the cost ranges from \$45 to \$52 for a 14-ounce can. The applicant estimates his monthly costs for his son's elemental formula, which was taken orally, were \$1,000 to \$1,500 per month.

### **Tube Feeding**

A feeding tube must be surgically placed. Local anesthesia is used to numb the throat. A flexible, lighted instrument called an endoscope is threaded to the stomach through the mouth, throat and esophagus. A skin incision is made through the abdomen and a needle introduced into the stomach. A snare is passed down the endoscope in order to capture a wire or suture that has been placed through the needle. A feeding tube, through which food will be sent directly into the stomach, is advanced over the wire into the stomach. Feedings can be started as soon as the next day.

Medical complications can occur with feeding tube placement. Major complications may include death, severe bleeding, perforation, protracted vomiting, and others. However, these occur in only one to two percent of cases, and the mortality rate is low at 0.2 – one percent. Most complications are minor and occur in approximately five to ten percent of cases. Usually, these

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<sup>8</sup> Medical Foods and Reimbursement, *Genetics in Medicine*, Vol. 12, Number 6, p. 367, June 2010.

<sup>9</sup> 21 C.F.R. 101.9(j)(8)

<sup>10</sup> Children's Milk Allergy and Gastrointestinal Coalition (Children's MAGIC) and APFED national internet-based survey.

consist of easily treatable and uncomplicated wound infections, bleeding or abdominal pain. Feeding tubes can also become clogged.<sup>11</sup>

## Defining the Problem

EGIDs are not very common. The national average shows 1: 2,000 people. Washington State's rate is estimated at 1:5,000.<sup>12</sup> Of the small number diagnosed with an EGID, a much smaller number will actually require elemental formula. These are typically the severe cases where individuals cannot tolerate adequate foods to meet their nutritional needs.

We were not able to obtain data on how many people with EGIDs require elemental formulas. The applicant has speculated that it is between 1:30,000 and 1:75,000 people; however, we were not able to confirm this number. We were able to obtain data and information from the Washington State Medicaid program, which serves approximately 20 percent of Washington State's population. Of the 1.3 million Washington residents on Medicaid,<sup>13</sup> only about 320 were diagnosed with EGIDs. Only 16 (five percent) of these individuals with EGIDs require medical foods, with only 10 receiving the formulas orally.<sup>14</sup>

Some individuals who suffer from these disorders may be unable to eat certain foods because they act as the trigger to incite an allergic response and lead to inflammation of the gastrointestinal tract. In severe cases, individuals are allergic to so many foods that they must obtain their nutrition through a special amino acid-based elemental formula. Elemental formulas are hypoallergenic and broken down to simple amino acids that are so small they do not elicit an allergic response.

Elemental formulas can be delivered orally or by feeding tube. If the treatment must be delivered through a feeding tube, the formula is generally covered by insurance. However, many private insurers will not cover the cost if the formula is delivered orally. The treatment can cost up to \$1,200 per month, and many families have great difficulty covering the out-of-pocket cost for the treatment.<sup>15</sup>

According to the American Gastroenterological Association, tube feeding should be considered when a patient is unable or unwilling to eat, has a functional gut, and there is a safe method of access. The decision to use a feeding tube should be made clinically, based on what is safest and most efficacious for the patient. There are potential side effects of installing a feeding tube, such as protracted vomiting.<sup>16</sup> In addition, there are social effects ranging from having to explain the

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<sup>11</sup> David E. Milkes, M.D., "Tube Feeding – Right or Wrong: The Medical, Legal and Ethical Issues," *Gastroenterology and Hepatology*, Stanford University Medical Center.

<sup>12</sup> Spergel, Jonathan M. et al., "Variation in Prevalence, Diagnostic Criteria, and Initial Management Options for Eosinophilic Gastrointestinal Diseases in the United States," *Journal of Pediatric Gastroenterology and Nutrition*, 2010, Nov. 3.

<sup>13</sup> Medicare-Medicaid Enrollee State Profile: Washington, Centers for Medicare & Medicaid Services, p. 1

<sup>14</sup> Washington State Medicaid Program, received 6/27/2013.

<sup>15</sup> Testimony from families of EGID sufferers

<sup>16</sup> American Gastroenterological Association Technical Review on Tube Feeding for Enteral Nutrition, American Gastroenterological Association, *Gastroenterology*, Vol. 108, No. 4, page 1,282.

tube extending from the nose to a backpack, or physical limitations due to fatigue, tenderness, or risk of injury to the feeding tube site.

A mandated benefit review in the state of Virginia revealed an additional challenge to the issue of insurance reimbursement of elemental formulas. They found that DME providers often mark up the formulas. If a carrier were to require the patient to purchase formula through a DME, and only pay a portion of the formula's cost, they may end up paying more out of pocket than if they purchased it from the manufacturer directly.<sup>17</sup>

The proposal, as written, may increase the total cost of health care because it includes broad language that includes all EGIDs. Elemental formulas are the recommended treatment for EoE, but they are not standard medical practice for EG.

The department encountered some challenges to studying this proposal due to the lack of data or studies related to:

- Washington's incidence of patients diagnosed with EGIDs, or who require elemental formula;
- the efficacy of elemental formula for EGIDs other than EoE; and
- adults who require elemental formula.

## **Current Coverage**

Elemental formulas are not covered in a uniform way in the insurance industry. When covered, they are sometimes under the pharmacy benefit and sometimes under the DME benefit.

### **Medicaid**

Medicaid covers enteral and oral administration of elemental formulas based on specific medical and nutritional considerations. This coverage is not administered consistently across Medicaid plans. Some are covered in the Enteral Nutrition Benefit (a separate benefit apart from pharmacy or DME) while others are covered under the pharmacy benefit. There are medical necessity criteria that must be met in order to qualify for Medicaid coverage for elemental formulas, such as inability to meet nutrient needs from food alone, metabolic and allergic conditions, low birth weight or failure to thrive. No prior authorization is required for tube-fed patients. However, prior authorization is required for oral nutrition products.<sup>18</sup>

### **Department of H Women, Infants and Children (WIC) Program**

The WIC program helps coordinate coverage of special formulas for children with the Medicaid program. WIC only provides access to 10 formulas through its usual process of issuing WIC checks to families so they can purchase these formulas at local stores. For all other formulas, WIC refers children to Medicaid. Medicaid will determine if the child is Medicaid eligible and if

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<sup>17</sup> Evaluation of Proposed Mandated Health Insurance Benefits, Evaluation of House Bill 615 and House Bill 669: Mandated Coverage of Amino Acid-Based Formulas, September 2008, Joint Legislative Audit and Review Commission of the Virginia General Assembly, p. 24.

<sup>18</sup> Washington State Health Care Authority Medicaid Provider Guide: Enteral Nutrition, [Chapter 182-554 WAC], p. D1-6.

the prescribed formula is medically necessary. If Medicaid rejects the prescription, the WIC-eligible child can be referred back to the WIC program. State WIC staff makes its own determination if the special formula (for example, an elemental formula) is medically necessary. If the formula is determined to be medically necessary, state WIC staff will arrange for a special purchase of the formula and have the formula delivered each month to the child's local WIC clinic. The child's caregiver will pick up the formula at their local WIC clinic.

### **Department of Health Newborn Screening Program**

For children not eligible for Medicaid, the Department of Health has a multi-state formula contract for PKU formulas and other metabolic formulas and medical foods at a reduced rate. The state laboratory has a distribution center that provides the formulas to the families. EGIDs are not part of the newborn screening program and are not included in this contract.

### **State-Purchased Plans**

According to the Health Care Authority (HCA), the Public Employee Benefits Board (PEBB) plans specifically cover medical foods and formulas to treat PKU as already required by state mandate. Some plans include elemental formulas to treat other conditions besides metabolic conditions but do not include EGID diagnoses. Some cover EGIDs but only when administered through a feeding tube. Here are some specific examples:

- The PEBB self-funded plans currently cover those formulas mandated for PKU and those delivered parenterally. These are covered under the DME and supplies benefit. We have no indication that these plans include patients with EGID diagnoses.
- The PEBB-insured managed care health plans would be impacted by this proposed mandate. Currently the PEBB Kaiser plan covers enteral supplements and formula (Ensure or elemental enteral formula) under the DME and supply benefit. Its standard contract language under Covered Drugs, Supplies, and Supplements includes the following definition:

"Medical foods and formulas necessary for the treatment of phenylketonuria (PKU), severe intestinal malabsorption, specified inborn errors of metabolism or other metabolic disorders".
- Kaiser pharmacy benefits for this condition are also available. Kaiser indicated that this condition is typically treated with specialized enteral formulas. Its pharmacy only dispenses parenteral formulas which are administered intravenously and dispensed through their home infusion pharmacy. Enteral formulas are typically given orally or through a feeding tube. They are currently covered under DME (as referenced above).
- Group Health indicates that it currently covers elemental formulas. It does not specify mode of entry into the body (i.e., oral or feeding tube). According to the HCA, the mandate could result in broadening their list of covered conditions to specify this diagnosis to their list of covered indications. Group Health did not supply the number of current patients, but stated it is currently paying out approximately \$2,000 annually for



each patient utilizing this elemental formula benefit. There is no indication this includes any PEBB members enrolled in Group Health.

## **Other States**

There are 14 states that mandate coverage of elemental formulas for EGIDs. For example, Arizona's mandate requires coverage for "amino acid-based formula that is ordered by a physician or by a registered nurse practitioner if:

1. The insured has been diagnosed with an eosinophilic gastrointestinal disorder.
2. The insured is under the continuous supervision of a physician or a registered nurse practitioner.
3. There is risk of a mental or physical impairment without the use of the formula."

Arizona's law also states that health plans "shall cover at least seventy-five per cent of the cost of the formula. The accountable health plan may limit the maximum annual benefit for formula under this section to twenty thousand dollars."<sup>19</sup>

## **Social Burden**

A recent study published in the *Journal of Allergy and Clinical Immunology* explored the social impact of living with EGIDs. It identified parent reports of EGIDs interfering with school, work, and other daily activities 58 percent of the time. It reported EGIDs interfering with meal preparation and eating about 75 percent of the time. There was frustration with people not understanding what it means to live with EGIDs and with health care providers not knowing how to treat children with EGIDs.

Elemental formulas are generally available to those who need them. They can be purchased over-the-counter. However, they are cost-prohibitive, making them financially unavailable to many families. These formulas are generally covered by insurance when administered by feeding tube; however, feeding tubes require surgery and should only be used when oral administration is not well-tolerated or a tube is medically necessary. As described earlier, there are physical and social impacts to living with a feeding tube. These range from having to explain the tube extending from the nose to a backpack or a lump under the shirt from a g-tube, to physical limitations due to fatigue or tenderness or risk of injury to the feeding tube site.

The level of public demand for this service is very low because the number of individuals who need these formulas is very low. However, those who need elemental formulas often have no other choice in obtaining basic nutrition.<sup>20</sup>

## **Financial Burden**

Inadequate insurance is a barrier to patients having access to elemental formulas, which are in some cases a patient's only source of nutrition. Families pay up to \$1,200 per month out of pocket to provide this necessary formula to their children, creating a large burden to them. Many

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<sup>19</sup> Arizona revised statute 36-2907.01.

<sup>20</sup> Anecdotal story provided by applicant from parent of a child with EGID

insurance carriers already cover elemental formulas when administered by feeding tube. However, a feeding tube is invasive and generally more expensive than receiving elemental formulas orally. According to the applicant, a feeding tube can cost an additional \$1,000 for surgical installation and at least \$1,000 month for supplies and pump rentals. Tube adjustments are necessary on a regular basis, which can cost an additional \$1,000 each. In addition, medical complications with feeding tube placement, such as severe bleeding, vomiting, perforation, and infections increase costs to the health care system due to visits to the emergency room and additional treatments and surgeries.<sup>21</sup>

The cost of elemental formulas is significant. It is substantially higher than regular baby formulas. A mandated benefit review in the state of Virginia provided a table from the Children's Milk Allergy and Gastrointestinal Coalition showing that it estimates regular baby formulas cost between \$113-213 per month, but elemental formula is in the range of \$252-473 per month,<sup>22</sup> and we have heard anecdotal stories of it costing up to \$1,200 a month for some families.

## **Proof of Efficacy**

There has not been a lot of study on EGIDs in general because they are uncommon. However, EoE has been studied more in recent years because it seems to be the most common.

A retrospective study of EoE conducted over 10 years at the Children's Hospital of Philadelphia reported, "Dietary therapy is the mainstay of our treatment. Removal of the offending food agents results in symptom resolution, histologic normalization of the esophagus, and no need for the chronic use of medication for patients with EoE. Thus, aggressive dietary restriction should be attempted whenever possible. An amino acid-based formula is frequently required..."

The study recommends dietary therapy because pharmacologic therapy must be used chronically, does not always result in healing of the esophagus, and has significant side effects. It identified no significant side effects of prolonged use of elemental formulas (orally or by feeding tube) and in most cases, it was possible to identify the specific food allergens within six months.<sup>23</sup>

The Division of Gastroenterology and Nutrition at the Children's Hospital of Philadelphia conducted a study from January 1, 1997 to January 1, 2000, on EoE patients to determine their response to elemental diet. This study concluded that the "elemental diet resulted in striking improvement in both symptoms and histologic evidence of disease in children and adolescents with EoE, as identified by strict diagnostic criteria."<sup>24</sup> This study further concluded that pharmacologic treatments like corticosteroids treat the symptoms without addressing the

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<sup>21</sup> David E. Milkes, M.D., "Tube Feeding – Right or Wrong: The Medical, Legal and Ethical Issues," *Gastroenterology and Hepatology*, Stanford University Medical Center.

<sup>22</sup> Evaluation of Proposed Mandated Health Insurance Benefits, Evaluation of House Bill 615 and House Bill 669: Mandated Coverage of Amino Acid-Based Formulas, September 2008, Joint Legislative Audit and Review Commission of the Virginia General Assembly.

<sup>23</sup> Chris A. Liacouras, et al., "Eosinophilic Esophagitis: A 10 Year Experience in 381 Children," *Clinical Gastroenterology and Hepatology*, 2005; 3:1198-1206.

<sup>24</sup> AM J Gastroenterol 2003;98:777-782. ©2003 by Am. Coll. Of Gastroenterology

underlying cause. “When used in combination with well-delineated diagnostic criteria, we conclude that elemental diet is not only effective but also the best treatment option.”<sup>25</sup>

Updated consensus guidelines for EoE state, “Dietary therapy continues to be effective in children given a diagnosis of EoE. The literature continues to demonstrate that the use of dietary therapy leads to near-complete resolution of both clinical and histologic abnormalities when compared with the administration of a strict elemental formula in allergic patients, elemental formula continues to be the most effective dietary therapy.” In addition, they state, “Dietary therapy should be considered in all children given a diagnosis of EoE. Preliminary observations suggest that dietary restriction should also be considered for motivated adult patients with EoE. When deciding on the use of a specific dietary therapy, the patient’s lifestyle, adherence to therapy, and family resources need to be considered. Consultation with a registered dietitian is strongly encouraged to ensure that proper calories, vitamins, and micronutrients are maintained.”<sup>26</sup>

There are no consensus recommendations for treatment of other EGIDs. The number of patients diagnosed with these other eosinophilic conditions may be too small to enable a scientifically valid study. However, some of the research can most likely be applied to other EGIDs where it is determined the trigger is specific food allergies. The studies cited above determined there were no significant side effects of the use of elemental formulas, making it a safe treatment when indicated. In addition, EGIDs affecting the stomach, intestine and colon are less likely to be allergic in nature than EoE, so this will be very uncommon.<sup>27</sup>

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<sup>25</sup> Jonathan E. Markowitz, M.D., et al., “Elemental Diet Is an Effective Treatment for Eosinophilic Esophagitis in Children and Adolescents,” *The American Journal of Gastroenterology*, Vo. 98, No. 4, 2003.

<sup>26</sup> Chris A. Liacouras, MD, et al., “Eosinophilic Esophagitis: Updated Consensus Recommendations for Children and Adults,” *Clinical Reviews in Allergy and Immunology*, page 13.

<sup>27</sup> APFED



## ASSESSMENT OF THE SUNRISE CRITERIA

### Social Impact

#### **To what extent is the benefit generally utilized by a significant portion of the population?**

This benefit is not generally utilized by a significant portion of the population. We estimate about 1:5,000 people diagnosed with an EGID, with a very small percentage of those diagnosed requiring elemental formula. Medicaid, which serves approximately 20 percent of Washington's population (1.3 million residents), reported only .02 percent (320 patients) enrolled in 2012 were diagnosed with EGIDs, and only 10 patients who required oral elemental formula.<sup>28</sup>

We estimate that 64 percent of patients will use medical foods for two years or less and only 19 percent using them for 5 years or more.<sup>29</sup>

#### **To what extent is the benefit already generally available?**

This benefit does not appear to be generally available through private insurance, although some will cover elemental formulas based on other underlying diagnoses such as failure to thrive or food allergy. In addition, it does not appear to be generally available through state-purchased health plans. These plans seem to only cover the formulas required for PKU and other metabolic conditions, which is an existing state mandate. It is widely available through the state Medicaid program.

#### **If the benefit is not generally available, to what extent has its unavailability resulted in persons not receiving needed services?**

Testimony provided at the public hearing revealed some families were not able to receive the needed services until they were forced to apply for Medicaid. A Swedish Medical Center pediatric gastroenterologist specialist at Swedish Medical Center testified that a majority of her EGID patients who require elemental formulas aren't able to afford it, causing her to prescribe less effective and more harmful steroid therapy.

#### **If the benefit is not generally available, to what extent has its unavailability resulted in unreasonable financial hardship?**

Families of EGID patients reported costs for these formulas exceeding \$1,200 per month. This has caused financial hardship for many of these families and in some cases families have had to go on Medicaid to address the hardship.

#### **What is the level of public demand for the benefit?**

The level of public demand for the benefit is low. However, in the small population that needs this benefit, the need is critical.

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<sup>28</sup> Washington State Medicaid Program, received 6/27/2013.

<sup>29</sup> Internet-based survey of self-reported data in 2012 by APFED

**What is the level of interest of collective bargaining agents in negotiating privately for inclusion of this benefit in group contracts?**

Unknown.

**Financial Impact**

**To what extent will the benefit increase or decrease the cost of treatment or service?**

This benefit will substantially decrease the cost of treatment for families dealing with EGIDs. These families currently pay up to \$1,200 per month for this treatment.

**To what extent will the coverage increase the appropriate use of the benefit?**

Coverage will most likely increase the appropriate use of the benefit because it will increase the number of individuals with access to these formulas covered by private insurance. Families who could not afford elemental formulas and were forced to use alternative treatments<sup>30</sup> that were less effective will most likely increase their utilization.

**To what extent will the benefit be a substitute for a more expensive benefit?**

For some, oral formulas will be a substitute for formulas via feeding tube when possible. Costs for the actual formula are comparable for both oral administration and that given through feeding tubes. There are additional costs for feeding tubes, making it the more expensive benefit.

**To what extent will the benefit increase or decrease the administrative expenses of health carriers and the premium and administrative expenses of policyholders?**

We did not receive estimates from carriers on the impact to administrative expenses. The low incidence rate of EGID diagnoses and even lower incidence rate of those requiring elemental formulas seem to indicate this would be a small cost.

**What will be the impact of this benefit on the total cost of health care services and on premiums for health coverage?**

We did not receive estimates from carriers on the impact on costs of health care services or premiums. However, this treatment will often be a trade-off for other treatments, such as corticosteroids or elemental formula by feeding tube, which they already cover.

**What will be the impact of this benefit on costs for state-purchased health care?**

The HCA does not indicate any fiscal impact on costs for state-purchased health care. The health plans affected by the proposal indicate few, if any, changes would be required to the scope of their current coverage. The conditions are rare, creating a very limited potential for HCA cost impacts.

The Office of the Insurance Commissioner's (OIC) fiscal note on HB 1216 stated it anticipates this coverage to be included in the 2016 federal essential health benefits because it is currently covered by the federal Medicaid and Employee Benefits Plans. However, if it is not included in

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<sup>30</sup> Examples given at the public hearing by Dr. Pisharody of Swedish Medical Center

the essential health benefits as anticipated, the state will be required to defray the costs in the Exchange. The OIC anticipates that this will apply to a low number of enrollees in the Exchange (about three individuals) at an estimated total cost of about \$100,000 per year.

**What will be the impact of this benefit on affordability and access to coverage?**

This benefit will increase access to elemental formulas for the small number of families in Washington who really need it, because it will cover the cost of these products.

**Efficacy**

**If a mandatory benefit of a specific service is sought, to what extent has there been conducted professionally accepted controlled trials demonstrating the health consequences of that service compared to no service or an alternative service?**

Two major studies conducted at Children’s Hospital of Philadelphia (see Proof of Efficacy on page 13 for details) concluded that elemental diets are highly effective and preferred over pharmacologic options. In addition, updated consensus recommendations published in *Clinical Reviews in Allergy and Immunology* recommend dietary therapy as an effective treatment and find that elemental formula continues to be the most effective dietary therapy.<sup>31</sup>

There is a lack of evidence about this treatment for other types of EGIDs. However, this seems to be primarily due to very small incidence of these disorders. Some of the research can most likely be applied to other EGIDs where it is determined the trigger is specific food allergies.

**If a mandated benefit of a category of health care provider is sought, to what extent has there been conducted professionally accepted controlled trials demonstrating the health consequences achieved by the mandated benefit of this category of health care provider?**

N/A

**To what extent will the mandated benefit enhance the general health status of Washington residents?**

Removing the financial factor from decisions on what treatment to choose will enable patients and their health care providers to make choices based on the provider’s clinical determination of what is the most effective treatment. Although it affects a small portion of Washington’s population, this benefit will enhance the health status of a few very ill citizens, and may decrease future hospitalizations by enabling appropriate treatment.

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<sup>31</sup> Chris A. Liacouras, MD, et al., “Eosinophilic Esophagitis: Updated Consensus Recommendations for Children and Adults,” *Clinical Reviews in Allergy and Immunology*.





## **DETAILED RECOMMENDATIONS TO THE LEGISLATURE**

The Department of Health concludes the proposal is in the best interest of the public. The benefits outweigh the costs of covering amino acid-based elemental formulas for treating food allergy-triggered EGIDs. However, we recommend the changes below to the draft legislation to clarify the mandate and address concerns raised during our review.

### **Rationale:**

#### **Social Impact**

The lack of consistent insurance coverage for elemental formulas makes them inaccessible for many consumers, despite the benefits being generally available. Patients and their families are making crucial treatment choices based on what they can afford, rather than what's in their best interest. These choices can result in adverse effects to the patients.

#### **Financial Impact**

The goal should be to drastically lower out-of-pocket costs on families paying for treatment of EGIDs. The low incidence of EGIDs, combined with the even lower number of EGID patients that need elemental formulas, appears to indicate a very small impact on costs to health plans and on premiums.

#### **Evidence of Health Care Service Efficacy**

There are different treatment options for patients with EGIDs. For those patients who can't tolerate sufficient foods to maintain adequate nutrition, elemental formulas can be highly effective and are often the best treatment option "when used in combination with well-delineated diagnostic criteria."<sup>32</sup> The studies only relate to EoE at this time. However, elemental diets are safe to administer and should be considered when treating other EGIDs where food allergies are the trigger.

#### **Challenges to Implementation as Drafted**

- We have strong concerns about placing the mandate in the existing PKU mandate and removing the PKU intent language because EGIDs should be a separate mandate. PKU is an inherited, incurable disorder where the body cannot process part of the protein, phenylalanine, which is found in the proteins of most food. This disorder requires lifelong treatment through a special metabolic elemental formula in order to avoid severe mental and physical difficulties. EGIDs are inflammatory disorders that impact the gastrointestinal system. EGIDs are often not lifelong, require different types of formulas than those for treatment of PKU, and may have other treatment options available in addition to elemental formulas.
- We feel it should be made clear in the mandate that elemental formulas should be used to treat the underlying cause of a disease. The mandate should be directed toward treatment

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<sup>32</sup> Jonathan E. Markowitz, M.D., et al., "Elemental Diet Is an Effective Treatment for Eosinophilic Esophagitis in Children and Adolescents," *The American Journal of Gastroenterology*, Vo. 98, No. 4, 2003.

where the trigger of an EGID is a food allergy, the individual is not able to consume adequate nutrition, and/or there is a failure to grow, which can be altered by dietary changes.

- Premera BlueCross stated that the proposal would require it to cover formulas that are available over-the-counter. It noted that insurance policies don't generally cover over-the-counter items, adding this type of mandate could lead to an increased number of mandates for other types of nutritional or dietary supplements or foods. However, we believe these concerns are minimal because:
  - Elemental formulas are classified by the FDA as medical foods, which are specially formulated and processed products for the partial or exclusive feeding of patients. They are intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles as established by medical evaluation. The FDA requires medical foods to be consumed or administered under the supervision of a physician.<sup>33</sup> We feel this definition addresses Premera's concern about covering over-the-counter items.
  - Medical foods are distinguished from the broader category of foods for special dietary use by requiring them to be used under medical supervision. Medical foods are specially formulated and processed for the patient who is seriously ill, or someone requires the product as a major treatment modality. We feel this addresses Premera's concern about coverage being required for additional dietary and nutrition supplements.

The Department of Health supports the addition of a mandate to require coverage of elemental formulas to treat EGIDs. However, we recommend some changes to the draft bill to address the challenges raised above:

- Do not amend the language in the PKU statutes, RCW 48.20.520, 48.21.300, 48.44.440, and 48.60.510. Instead, create new subsections under chapters 48.20, 48.21, 48.22, and 48.60 RCW to specifically address EGIDs.
- Include language to clarify the mandate applies to “elemental formulas” or “medical foods.”
- Include language that requires the elemental formulas/medical foods to be medically necessary and ordered by and under the supervision of a physician or other health care provider with prescriptive authority.

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<sup>33</sup> 21 C.F.R. 101.9(j)(8)

## **REBUTTALS TO DRAFT REPORT**

The department shared draft recommendations with interested parties and invited comments before finalizing the report. We received two letters of comment, which are summarized below.

### **Jeff Schwartz, Sunrise Review Applicant**

“I fully support the (Department of Health’s) findings that “the proposal’s concept is in the best interest of the public and that the benefits outweigh the costs of covering amino acid-based elemental formulas for treating EGIDs” and the three recommended changes to the draft bill. I do not have any recommended changes to the proposal as written. Thank you and the (Department of Health) for your consideration and detailed research it took to make this proposal.”

### **Department Response**

Mr. Schwartz’s comments support the recommendations as written so no changes were required in the report.

### **Mother of Son with EoE**

The commenter wrote that there are additional eosinophilic disorders that were not included in the report. She also wrote that there are varying degrees of allergies and tolerance to foods.

In addition, she provided information specific to her son’s EoE, including information about recommendations from her son’s dietician and allergist that her son should be on elemental formula to help him gain weight, which their insurance provider will not cover. She further discussed physical limitations her son has, including not being able to exercise because he already has trouble gaining weight and this would exacerbate it. There are other possible underlying conditions that contribute to her son’s feeding problems and food trials can be very expensive. She also mentioned issues with state disability insurance for her son and that EoE should be on the social security’s list of approved disabilities.

### **Department Response**

The department did not make any changes to the recommendations in response to these comments:

- The EGIDs referenced in the report are the most common ones that we found in our research. The recommendation does not specify which EGIDs should be mandated for coverage.
- State disability insurance carriers are included in the draft mandate.
- The other comments were outside the scope of this review.



# Appendix A

## Applicant Report



# ***HB1216: Concerning insurance coverage of treatment of eosinophilia gastrointestinal associated disorders***

## **Sunrise Review Criteria (From RCW 48.47.030)**

Date: April 2013

### **Applicant**

This Sunrise Review Application is submitted by **Jeffrey Schwartz** of Kirkland, Washington.

**Jeffrey Schwartz** is a proponent of HB 1216, which requires health insurers to provide coverage for elemental formula, classified as a medical food by the Food and Drug Administration (FDA), for the treatment and diagnosis of Eosinophilic Gastrointestinal Disorders (EGIDs), regardless of delivery method. These medical foods can be administered both orally and enterally (via a feeding tube). This legislation seeks equal coverage regardless of delivery method.

Reimbursement became a personal quest for Jeff when his son, Jacob, was diagnosed with Eosinophilic Gastritis at age of 6 months. For 3 years, Jacob drank a medical food called Elecare. During that time, Jeff's insurance provider dropped coverage for his son's medical food, leaving the on average monthly cost of \$1,200 for his family to shoulder.

This Sunrise Review Application provides details specific to the required criteria of Social Impact, Financial Impact, and Service Efficacy. In addition there are supplemental criteria unique to the treatment of EGIDs which should be considered along with the criteria required in RCW 48.47.030.

### **Definitions**

**Medical foods** – For the remainder of this document, medical foods and elemental formula will be used interchangeably. The Food and Drug Administration defines a medical food as {defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3))} as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."<sup>1</sup>

**EGIDs** – Eosinophilic Gastrointestinal Disorders. For the remainder of this document, EGIDs and Eosinophilic Gastrointestinal Disorders will be used interchangeably.

<sup>1</sup> <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MedicalFoods/default.htm>

Based on the availability of relevant information, the following criteria shall be used to assess the impact of proposed mandated benefits:

## 1. The Social Impact:

A recent published study in *The Journal of Allergy and Clinical Immunology*, February 2013, explored the social impact of living with Eosinophilic Gastrointestinal Disorders (EGIDs): “Participants reported that EGIDs interfered with school, work, and other daily activities 58.0% of the time, social events with friends or family 65.8% of the time, meal preparation 74.5% of the time, and eating a meal 74.1% of the time. Participants reported that 76.6% of the time they felt frustrated that other people did not understand what it meant to live with EGIDs, and 59.9% of the time they felt frustrated that their healthcare provider did not understand how to respond to their or their child’s EGID.”<sup>1</sup>

Personally, I can relate to the survey findings above as my family had to learn to adapt our way of life to cope with our son’s diagnosis of Eosinophilic Gastritis (EG). My son had a rare form of EG where he had multiple food allergies and required medical food as a sole and supplemental source of nutrition. We started with zero safe foods and only after performing 3 week food trials, were able to slowly add specific foods back to his diet. During these successful and failed food trials, Jacob drank Elecare – a medical food – as, firstly his sole source, and later as supplemental nutrition. Our goal was to discover enough safe foods to create a limited but complete and nutritious diet for Jacob.

Our journey began when Jacob turned 3 months. We started noticing that he often spit up excessively after eating. For the next 3 months, we often took Jacob to the Pediatrician’s office looking for advice and answers to his spit-up issues. We were given an anti-reflux medicine and told that some babies spit-up a lot. At his 6 months check-up, we were diagnosed with failure-to-thrive – Jacob’s growth chart had gone down as opposed to up resulting in a 3 pound weight loss. Consequently, we sought out a Pediatric Gastroenterologist and spent the next month looking for the cause – including countless diagnostics tests, an endoscopy, and a week stay in the hospital where he was on a feeding tube. We were very fortunate to have found a Gastroenterologist who was familiar with EGIDs and who requested an endoscopy with biopsies – it this procedure that provided us his diagnosis.

Receiving a diagnosis and starting treatment at 7 months is unfortunately both early and uncommon. The supplemental section in this document has data based on an internet survey of how long diagnoses take – we were lucky. Merely receiving our diagnosis was only just the beginning. Almost every aspect of our family’s life changed. Whether it was day-to-day activities like play dates and meal planning or scheduled events like summer vacations and school functions, it seemed like everything was impacted by this disorder in some way.

<sup>1</sup> Julia Eismín, Gillian Mayman, Wendy Book, Harvey L. Leo, Noreen Clark: Impact of Eosinophilic Disorders On Daily Activities and Frustration with Healthcare Provider Interactions. *The Journal of Allergy and Clinical Immunology*, Volume 131, Issue 2, Supplement  
<http://download.journals.elsevierhealth.com/pdfs/journals/0091-6749/PIIS0091674912033155.pdf>



(i) To what extent is the benefit generally utilized by a significant portion of the population?

Eosinophilic Gastrointestinal Disorders (EGIDs) are tracked by the National Organization for Rare Disorders (NORD).<sup>1</sup> It is believed that a significant portion of Washington’s population will not require this benefit.

There is no definitive answer to how many people are diagnosed with an EGID. The most recent research shows that there are 52 people per 100,000 or 1:2,000 diagnosed with Eosinophilic Esophagitis.<sup>2</sup> Specific to Washington State the incident rate was found to be 20 to 30 people per 100,000 for EoE or 1:3,400 to 1:5,000.<sup>2</sup>

Not all people diagnosed with an EGID require medical foods for treatment. Only the acutely ill diagnosed with an EGID require medical food as a supplement or sole source of nutrition.

The following questions would be helpful to get actual data from the Office of the Insurance Commissioner/Department of Health:

1. How many people in Washington are diagnosed with EGIDs? (below are the relevant insurance codes)
  - a. Eosinophilic Esophagitis – 530.13
  - b. Eosinophilic Gastritis – 535.7
  - c. Eosinophilic Gastroenteritis – 558.41
  - d. Eosinophilic Colitis – 558.42
2. What is the breakdown of people in Washington using medical food – specifically elemental formula – by diagnosis?

Merely knowing the number of people diagnosed with EGIDs is not sufficient to understanding how many people would benefit from using medical foods as a treatment. Only the acutely ill diagnosed with an EGID require medical food as a supplement or sole source of nutrition.

Option 1 Nutrition Solutions is a provider of enteral formulas and nutritional supplements along with enteral pumps and ancillary supplies<sup>3</sup> – they serve Arizona, Colorado, Nevada, Oregon, and Washington among other states. Based on data (current through April 2013) only 7.65% of their business relates to providing Neocate and Elecare in Washington – the predominate treatment for EGIDs – with 3.37% of their clients drinking these medical foods and 4.28% receive them via an enteral tube. The data relating to diagnosis is incomplete, but, based on the information provided; only 0.97% of their patients were diagnosed with an EGID. These numbers are roughly in line with the estimates above, and when combined with the actual data from the OIC and DOH hopefully help to pinpoint real numbers for who is impacted in Washington.

An Internet-based survey of self-reported data in 2012 collected by the American Partnership for Eosinophilic Disorders (a national non-profit patient advocacy organization) based on input across the United States, showed that:

- 64% of patients only used a medical food for 2 years or less
- 22% using it for less than 6 months
- 19% using medical food for 5 years or more

<sup>1</sup> <http://www.rarediseases.org/rare-disease-information/rare-diseases/byID/1160/viewAbstract>

<sup>2</sup> Spergel, Jonathan M. et al., Variation in Prevalence, Diagnostic Criteria, and Initial Management Options for Eosinophilic Gastrointestinal Diseases in the United States, *Journal of Pediatric Gastroenterology and Nutrition*, 2010 Nov. 3 (Epub ahead of print), at 3. <http://www.ncbi.nlm.nih.gov/pubmed/21057327>

<sup>3</sup> <http://option1nutrition.com/Services.html>

## (ii) To what extent is the benefit already generally available?

In Washington State Medicaid and the Washington State Health Insurance Pool (WSHIP) provide medical food coverage for the treatment and diagnosis of Eosinophilic Gastrointestinal Disorders (EGIDs).

There is no consistency in the way health plans offer medical food coverage for the treatment of EGIDs across the nation. Some plans offer benefits under durable medical equipment (DME), pharmacy benefits, or special arrangement (eg. medical food benefits).

An Internet-based survey of self-reported data in 2012 collected by the American Partnership for Eosinophilic Disorders (a national non-profit patient advocacy organization) based on input across the United States, showed that for those who have insurance coverage:

- 31% were covered under DME
- 9% under pharmacy benefits
- 7% special arrangement
- The remainder were unsure or did not have coverage

Frequently, there is confusion determining if a plan offers the necessary coverage. For example, based on reading the text of our insurance policy as a layman, we felt that EGIDs should be covered as a result of the wording of our plan: ‘patients with specific conditions, including...’ After being denied and pursuing the two stage appeal process, we were clearly told that our policy does not provide coverage. In my opinion, it is difficult to understand that EGIDs are not covered. My self-funded insurance plan had the following medical food coverage:

“Benefits for medically necessary enteral nutritional therapy [are covered] only when it is administered via a feeding tube and for patients with *specific conditions, including* inborn errors of metabolism (such as phenylketonuria (PKU))”

When we read our policy, the ‘including’ portion seemed open to other disorders beyond PKU. Only after being denied we were told it was not.

The following questions would be helpful to get actual data from the Office of the Insurance Commissioner/Department of Health:

1. What section of the WA health policies (list below) offer coverage for medical food? Does this explicitly include coverage for EGIDs? Is the coverage for enteral, oral, or both?
  - a. Medicaid

- b. Public Employees Benefits Board (PEBB)
  - c. Basic Health (BH)
  - d. Essential Health Benefits (EHB)
  - e. Washing State Health Insurance Pool (WSHIP)
2. What section of the WA health policies (list below) offer coverage for medical food? Does this explicitly include coverage for EGIDs? Is the coverage for enteral, oral, or both?
  - a. Asuris Northwest Health
  - b. ODS Health Plan, Inc.
  - c. Group Health Cooperative
  - d. Premera Blue Cross
  - e. Group Health Options
  - f. Regence BlueCross BlueShield of Oregon
  - g. Kaiser Foundation Health Plan of the Northwest
  - h. Regence BlueShield of Washington
  - i. LifeWise Health Plan of Washington
  - j. Time Insurance Company (Assurant Health)

An Internet-based survey of self-reported data in 2012 collected by the American Partnership for Eosinophilic Disorders, (a national non-profit patient advocacy organization) based on input across the United States, showed that:

- 30% of EGID patients had no insurance coverage
- 20% have coverage through state provided insurance
- 14% had full insurance coverage through a commercial provider
- The remaining patients only had partial coverage, were on a federal plan, or used a combination of commercial, state, and federal

**(iii) If the benefit is not generally available, to what extent has its unavailability resulted in persons not receiving needed services?**

Cost is the single biggest barrier to receiving treatment – if a family does not have insurance coverage.

Medical foods are expensive and must be purchased through a local medical equipment distributor like Option 1 Nutrition Solutions or through the pharmaceutical company directly. Here are examples of the cost for a can of powered medical foods – used for the treatment of Eosinophilic Gastrointestinal Disorders (EGIDs).

Neocate Jr. Unflavored – Nutricia sells a case of 4 14oz cans for \$139 – that is \$35 per can<sup>1</sup>

Elecare Jr. Unflavored – Abbott Labs sells a case of 6 14oz cans for \$210.12 – that is \$35 per can<sup>2</sup>

There are three factors that determine cost for these medical foods: cost per can, cans consumed per day, and calories per fl. oz.

Medical foods are very expensive due, in part, to complex scientific manufacturing processes, cost of raw materials and product quality assurance required for these at-risk individuals. The Food and Drug Administration (FDA) classifies medical foods separately and does not require them to go through the

same clinical trials as prescription drugs because of the limited number of patients available for testing. As a result, medical foods are available without prescription, and health insurance companies consequently have refused to cover them despite their medical necessity. Insurance companies currently cover the cost of medical foods only when administered by enteral tube feeding, even though tube feeding is not always the least medically invasive or most cost effective option available. They will not cover the cost of the same medical food if the patient can consume the product by mouth.

Elemental Formulas are a medical food and as such must be administered under the care of a physician. The physician determines the ratio of powder to water to ensure the treatment meets the nutritional needs of the patient for their age. The physician sets how many calories per fl. oz. The calorie amounts per fluid ounce determine the quantity of cans consumed per day. If the physician determines the patient needs a higher calorie per fl. oz., the number cans consumed per day is higher.

My 3 year old son was consuming 1 can of formula every 2 days. At that time we were using Option 1 Nutrition Solutions, a local medical food distributor, and our medical food costs ranged from \$900 to \$1,200 a month.

The average cost for medical foods is based on the three factors above, however a rough estimate of \$1,000-\$1,500 a month is reasonable to assume.

Another barrier to receiving treatment is discovering how and where to purchase these medical foods. In our case, we initially had insurance coverage for the medical foods and our insurance provider selected Option 1 Nutrition Solutions as our distributor. We received a prescription from our specialist, just as we would for any other pharmaceutical, and Option 1 Nutrition Solutions delivered them to our house. Once our insurance carrier dropped coverage we continued to use Option 1 Nutrition Solutions for obtaining Jacob's Elecare, but had to start paying out of pocket.

Option 1 Nutrition Solutions is a provider of enteral formulas and nutritional supplements along with enteral pumps and ancillary supplies<sup>3</sup> - they serve Arizona, Colorado, Nevada, Oregon, Washington, among other states. Based on data (current through April 2013) people in Washington pay more often out of pocket than the other states - 11.43% of patients pay cash in Washington as opposed to the average of 2.42% (based on patients who receive Neocate and Elecare). On average, patients in Washington are having to pay out of pocket for this treatment compared to other states.

<sup>1</sup> <https://www.neocate.com/shop/>

<sup>2</sup> <http://www.abbottstore.com/therapeutic-nutrition/elecare/icat/elecare&source=ele>

<sup>3</sup> <http://option1nutrition.com/Services.html>

#### (iv) If the benefit is not generally available, to what extent has its unavailability resulted in unreasonable financial hardship?

There are two aspects regarding unreasonable financial impact that are important to consider – unreasonable financial impact to the 1) patient and their family and 2) insurance providers.

The following questions would be helpful to get actual data from the Office of the Insurance Commissioner/Department of Health:

1. Given Washington State provides coverage through Medicaid – what is the average cost for medical foods spent annually per patient?
2. Given Washington State provides coverage through WSHIP – what is the average cost for medical foods spent annually per patient?

This information may help provide real world data on the likely cost to the patients.

#### Financial impact: The patient and their family

As mentioned in criteria 2.iii, the largest single barrier to receiving treatment – if not covered by insurance – is cost.

The cost impact to families hits the middle class the hardest. These families are spending approximately \$1,000 per month, the equivalent of an additional mortgage payment, on medical food. Not many middle class families can afford this additional expense along with the additional medical expense they incur as part of having a chronically ill child.

One definition for Financial Hardship<sup>1</sup> is:

Financial hardship means that you are suffering "extreme privation" and "suffering" because you don't have enough money. Basically, you don't have the money necessary to provide the basic comforts and necessities of life.<sup>1</sup>

The small percentage of families living with EGIDs in WA who require medical food as treatment do have a hard time finding the money necessary to provide basic comforts, necessities of life, and pay for the cost of this physician prescribed treatment.

#### Financial impact: Insurance providers

Many insurance providers cover the cost for a more expensive and invasive treatment – through an enteral feeding tube. Feeding tubes are medically necessary in some cases, though there are a number of additional expenses involved in surgically implanting and maintaining a feeding tube.

The cost of oral and enteral treatment start with the same base cost – medical foods. The exact same formula can be taken orally or administered through a feeding tube. The additional costs of enteral feeding come from the initial surgical procedure (\$1,000+), disposable supplies (\$500-\$1,000 per month), pump rental fees, feeding tube maintenance and replacement (\$1,000+ ranging from 1-3 times a year)<sup>2</sup>.

Drinking medical foods, when an option, is always a cost effective treatment option.

When our medical food coverage dropped, we discussed the option of having a surgically implanted feeding tube for Jacob. A feeding tube is a lifelong commitment and one that should never be taken lightly. However, when faced with the financial hardship of paying for oral medical food, it was an option we researched. As I mentioned above, feeding tubes are medically necessary at times, and expensive to the insurance carriers. Hopefully there are not cases in Washington where a feeding tube was chosen over oral consumption just to help defer cost.

Another aspect of cost for the carriers is covered in 2.i – the cost associated with not treating. If the medical food is not covered and the patient is left to remain acutely ill, there are additional costs for ongoing care, visits to the hospital, future medical expenses because the gastrointestinal tract tissue is inflamed, resulting fibrosis sets in, and remodeling of the organ tissue takes place. All of these are preventable if the physician prescribed treatments are followed.

<sup>1</sup> [http://www.ehow.com/facts\\_5652530\\_financial-hardship\\_.html#ixzz2NipU3pfA](http://www.ehow.com/facts_5652530_financial-hardship_.html#ixzz2NipU3pfA)

<sup>2</sup> Based on a personal story from a family in Washington on their costs for enteral feeding.

#### (v) What is the level of public demand for the benefit?

Given the very limited population of people impacted in Washington, there is very low public demand for this benefit. However, the people impacted are extremely passionate about seeing insurance coverage.

An Internet-based survey of self-reported data in 2012 collected by the American Partnership for Eosinophilic Disorders, (a national non-profit patient advocacy organization) based on input across the United States, showed that: 90% of the respondents indicated that formula coverage was “extremely important” to them, and that 67% of respondents reported having used medical foods for the treatment of their Eosinophilic Gastrointestinal Disorder. 4% of the respondents indicated that they lived in Washington, and 6% indicated that Washington State was where their insurance policy originates.

Further the same survey showed that of the 67% that have used medical food to treat an EGID:

- 44% had full insurance coverage
- 17% had partial insurance coverage
- 4% use state insurance programs
- 30% had no insurance coverage

Of the 67% of people that have used medical food to treat an EGID:

- 14% had standard plan coverage
- 46% used the appeal process and/or doctor letter to receive coverage
- 30% had no coverage.

Seventy-six percent (76%) of people that have used medical food for the treatment of an EGID do not have coverage based on their standard policy benefits.

#### (vi) What is the level of interest of collective bargaining agents in negotiating privately for inclusion of this benefit in group contracts?

There is a very limited population of impacted people in Washington. Statistically speaking, the number of people impacted who are on Public Health Plans are also on average very limited. As a result, there should be no impact on collective bargaining based on this benefit.

## 2. The financial impact:

An important aspect of assessing financial impact is the small population which Eosinophilic Gastrointestinal Disorders (EGIDs) affects in Washington State. Due to having such a small population, the financial impact is often cited as having *little to no impact* (examples cited below). Obtaining concrete data from within Washington State from section 1.i should help add clarity the small extent of the expected fiscal impact.

### (i) To what extent will the benefit increase or decrease the cost of treatment of service?

Providing coverage for medical food, regardless of delivery method, has the opportunity to decrease the overall cost for treating Eosinophilic Gastrointestinal Disorders (EGIDs). This is due to reducing the need for hospital stays and leveraging the less expensive treatment option for those diagnosed with EGIDs.

When patients are not receiving adequate treatment, they often find themselves either extremely dehydrated or malnourished which often leads to hospital stays and/or visits to the emergency room.

A 24hr hour hospital stay for intravenous feeding is reimbursed by commercial insurance at over \$5,000, this includes fees for doctors and mandatory lab studies for an acutely ill patient. The ability to receive proper treatment at home can help avoid these costly hospital stays and unnecessary medical expenses.

### (ii) To what extent will the coverage increase the appropriate use of the benefit?

Increased coverage is not expected to increase the use of this treatment.

Option 1 Nutrition Solutions is a provider of enteral formulas and nutritional supplements along with enteral pumps and ancillary supplies<sup>1</sup> - they serve Arizona, Colorado, Nevada, Oregon, Washington, among other states. Based on data (current through April 2013) the percentage of patients they provide Neocate and Elecare is very similar across these states.

Percentage of patients using Neocate and Elecare:

- Arizona – 8.98%
- Colorado – 7.09%
- Nevada – 8.62%
- Oregon – 8.42%
- Washington – 5.65%

Arizona and Oregon have laws mandating coverage for medical foods for the treatment of Eosinophilic Gastrointestinal Disorders (EGIDs) whereas Colorado, Nevada, and Washington do not. Given the statistically close percentages of people in each state suggests that regardless of insurance coverage mandates, the use of these medical foods as treatment remain the same.

<sup>1</sup> <http://option1nutrition.com/Services.html>

### (iii) To what extent will the benefit be a substitute for a more expensive benefit?

There are two methods for administering medical foods for the treatment of Eosinophilic Gastrointestinal Disorder (EGIDs) – enteral and oral. Oral feeding is more cost effective – as described in criteria 2.iv. Current policies often provide coverage for enteral treatment. Providing coverage for oral treatment will enable parity between enteral and oral and enable a substitute for a more expensive benefit.

Option 1 Nutrition Solutions is a provider of enteral formulas and nutritional supplements along with enteral pumps and ancillary supplies<sup>1</sup> - they serve Arizona, Colorado, Nevada, Oregon, Washington, among other states. Based on data (current through April 2013) all patients that pay out of pocket for Neocate and Elecare in Washington drink these medical foods – as opposed to tube fed. Washington patients that are tube feed are largely covered through State Programs – like Medicaid – or by private insurance.

<sup>1</sup> <http://option1nutrition.com/Services.html>

### (iv) To what extent will the benefit increase or decrease the administrative expenses of health carriers and the premium and administrative expenses of policyholders?

Providing coverage for medical food – regardless of delivery method – has the opportunity to decrease the administrative costs for treating Eosinophilic Gastrointestinal Disorders (EGIDs). This is due to no longer requiring lengthy appeal processes for patients diagnosed with EGIDs.

An Internet-based survey of self-reported data in 2012 collected by the American Partnership for Eosinophilic Disorders, (a national non-profit patient advocacy organization) based on input across the United States, showed that:

- 52% of people had to use a doctor’s letter or appeal process in order to get coverage
- 16% had coverage based on their policies
- The remaining 32% had no coverage – often times after a lengthy appeal process

Many families like mine went through two or more levels of appeals seeking medical food insurance coverage. After my insurance carrier denied our claim for medical food reimbursement, we had both Jacob’s Gastroenterologist, Pediatrician, and Nutritionist write letters proving the medical need. Over a period of 3 months, we called our carrier on the phone at times daily, had our doctors call, and followed the full extent of the appeal process – requiring many hours of our time and from our insurance carrier. In the end, we were denied. Our final optional appeal was our last chance given the language of our insurance policy.

Providing coverage for medical foods has the opportunity to reduce the amount of administrative expenses required by insurance providers.



#### (v) What will be the impact of this benefit on the total cost of healthcare services and on premiums for health coverage?

Thirteen States have insurance coverage for medical food for those with Eosinophilic Gastrointestinal Disorders (see additional criteria for a list of States with coverage). Below are some of their findings for the impact on premiums and financial impact:

Arizona – Legislation was signed into law without a fiscal note (because there was no anticipated fiscal impact)<sup>1</sup>

Ohio - “Not a real problem, replies Senator Krebs. This would raise premiums 1.6 pennies a year for the average family.”<sup>2</sup>

California – “AB 2174 is not expected to have any noticeable long-term cost impacts”<sup>3</sup>

“2 pennies” is often cited as the impact to insurance premiums when coverage for medical foods for the treatment of EGIDs is included. This is largely due to the very small population impacted across the nation and the fact that only the most acutely ill people with EGIDs require medical food for treatment.

<sup>1</sup>

[http://www.azleg.gov/FormatDocument.asp?inDoc=/legtext/47leg/2r/summary/s.2364health.doc.htm&Session\\_ID=83](http://www.azleg.gov/FormatDocument.asp?inDoc=/legtext/47leg/2r/summary/s.2364health.doc.htm&Session_ID=83)

<sup>2</sup> [http://articles.cnn.com/2000-03-13/health/baby.food.fight\\_1\\_food-supplement-baby-formula-neocate?\\_s=PM:HEALTH](http://articles.cnn.com/2000-03-13/health/baby.food.fight_1_food-supplement-baby-formula-neocate?_s=PM:HEALTH)

<sup>3</sup> [http://www.chbrp.org/documents/ab\\_2174\\_report.pdf](http://www.chbrp.org/documents/ab_2174_report.pdf)

#### (vi) What will be the impact of this benefit on costs for state-purchased healthcare?

There is no anticipated impact on costs for state-purchased healthcare. The fiscal note for HB 1216<sup>1</sup> noted no fiscal impact.

<sup>1</sup> <https://fortress.wa.gov/binaryDisplay.aspx?package=32964>

#### (vii) What will be the impact of this benefit on affordability and access to coverage?

As mentioned above in 1.iv and 2.iii, cost is a major factor when accessing medical foods. Receiving insurance coverage would have a positive impact on affordability for patients, insurance providers, and access to medical foods.

### 3. Evidence of healthcare service efficacy:

Eosinophilic Gastrointestinal Disorders (EGIDs) are a family of four disorders:

- Eosinophilic Colitis (EC): large intestine
- Eosinophilic Esophagitis (EoE): esophagus
- Eosinophilic Gastritis (EG): stomach
- Eosinophilic Gastroenteritis (EGE): stomach and small intestine

An Internet-based survey of self-reported data in 2012 collected by the American Partnership for Eosinophilic Disorders (a national non-profit patient advocacy organization) based on input across the United States, showed that:

- 78.5% of the respondents were diagnosed with Eosinophilic Esophagitis (EoE)
- 17.6% with Eosinophilic Gastroenteritis (EGE)
- 8.8% Eosinophilic Colitis (EC)
- 4.6% with Eosinophilic Gastritis (EG)
- 7.3% undiagnosed

(NOTE: the math does not add up to 100% because for this survey people could select multiple diagnoses).

Given the prevalence of Eosinophilic Esophagitis (EoE), much of the research cited below refers to EoE.

**(i) If a mandatory benefit of a specific service is sought, to what extent has there been conducted professionally accepted controlled trials demonstrating the health consequences of that service compared to no service or an alternative service?**

At present, there are two main treatments recommended for Eosinophilic Gastrointestinal Disorders (EGIDs): dietary management and topical and/or systemic corticosteroids. It has been demonstrated that medical foods are effective in treating EoE. In a series of 160 patients, 158 had normal esophageal biopsies after utilizing an elemental diet.<sup>1</sup> Medical foods, specifically elemental formulas, have been shown to be 98% effective.

Another study showed that an elemental diet resulted in “striking improvement in both symptoms and histologic evidence of disease in children and adolescents with EoE, as identified by strict diagnostic criteria”.<sup>2</sup>

<sup>1</sup> Liacouras CA, Spergel JM, Ruchelli E, et al. Eosinophilic esophagitis: a 10-year experience in 381 children. Clin Gastroenterol Hepatol. 2005; 3:1198-206  
<http://www.ncbi.nlm.nih.gov/pubmed/16361045>

<sup>2</sup> Markowitz JE, Spergel JM, Ruchelli E, Liacouras CA Elemental Diet Is an Effective Treatment for Eosinophilic Esophagitis in Children and Adolescents. Am J Gastroenterol 2003;98:777–782.  
<http://www.ncbi.nlm.nih.gov/pubmed/12738455>

(ii) If a mandated benefit of a category of healthcare provider is sought, to what extent has there been conducted professionally accepted controlled trials demonstrating the health consequences achieved by the mandated benefit of this category of healthcare provider?

According to the Consensus Recommendations,<sup>1</sup> which provides clinical and histopathology guidance for the diagnosis and treatment of Eosinophilic Gastrointestinal Disorders (EGIDs), dietary therapy as an effective treatment is continually recommended.<sup>2,3</sup> Three dietary regimens have been shown to be effective: “(1) strict use of an amino acid–based formula, (2) dietary restriction based on multimodality allergy testing, and (3) dietary restriction based on eliminating the most likely food antigens.”<sup>1</sup> The study notes that “similar results (clinical and histologic response) have been documented when using either method of dietary restriction; however, when compared with the administration of a strict elemental formula in allergic patients, elemental formula continues to be the most effective dietary therapy.”<sup>4</sup>

<sup>1</sup> Eosinophilic esophagitis: Updated consensus recommendations for children and adults, *J Allergy Clin Immunol.*, Volume 128, Issue 1, Pages 3-20.e6, July 2011.  
<http://www.ncbi.nlm.nih.gov/pubmed/21477849>

<sup>2</sup> Spergel JM, Brown-Whitehorn TF, Beausoleil JL, Franciosi J, Shuker M, Verma R, et al. 14 years of eosinophilic esophagitis: clinical features and prognosis. *J Pediatr Gastroenterol Nutr.* 2009;48:30–36  
<http://www.ncbi.nlm.nih.gov/pubmed/19172120>

<sup>3</sup> Spergel JM. Eosinophilic esophagitis in adults and children: evidence for a food allergy component in many patients. *Curr Opin Allergy Clin Immunol.* 2007;7:274–278  
<http://www.ncbi.nlm.nih.gov/pubmed/17489048>

<sup>4</sup> Chehade M, Aceves SS. Food allergy and eosinophilic esophagitis. *Curr Opin Allergy Clin Immunol.* 2010;10:231–237  
<http://www.ncbi.nlm.nih.gov/pubmed/20410819>

(iii) To what extent will the mandated benefit enhance the general health status of the state residents?

Eosinophilic Gastrointestinal Disorders are chronic allergic diseases that may cause nausea or vomiting, diarrhea, failure to thrive (poor growth or weight loss), abdominal or chest pain, reflux that does not respond to usual therapy, difficulty swallowing, food impactions, gastro paresis (delayed emptying of the stomach), anorexia (poor appetite), bloating, blood in the stool, and/or malnutrition.

Patients having access to mandated insurance coverage of prescribed medical foods may be more likely to follow the prescribed treatment and therefore be more likely experience a resolution of symptoms.

Families in the state of Washington have expressed confusion and frustration regarding inconsistent or non-existent insurance coverage or reimbursement for medical foods that has been recommended by

their health care provider for the treatment of an Eosinophilic Gastrointestinal Disorders. As a result, some families are paying out of pocket for the required expensive medical foods.

An Internet-based survey of self-reported data in 2012 collected by the American Partnership for Eosinophilic Disorders, (a national non-profit patient advocacy organization) based on input across the United States, showed that 90% of the respondents indicated that formula coverage was “extremely important” to them, and that 67% of respondents reported having used medical foods for the treatment of their Eosinophilic Gastrointestinal Disorder. 4% of the respondents indicated that they lived in Washington, and 6% indicated that Washington State was where their insurance policy originates. 17% of respondents indicated that in a 12-month period, they estimated paying \$2001-\$5,000 out of pocket for formula-related costs.

## The department may supplement these criteria to reflect new relevant information or additional significant issues.

In addition to the required criteria above, the following additional criteria may have a bearing on helping to determine the need for medical food coverage in Washington State, regardless of delivery method.

### How are Eosinophilic Gastrointestinal Disorders diagnosed?

Endoscopy is the sole method of diagnosis. For children, endoscopy is considered surgery and requires full anesthesia.

The Diagnostic guidelines from the Updated Consensus Recommendation states, “EoE [Eosinophilic Esophagitis] is a clinicopathologic disease. Clinically, EoE is characterized by symptoms related to esophageal dysfunction. Pathologically, 1 or more biopsy specimens must show eosinophil-predominant inflammation.”<sup>1</sup> This indicates that an endoscopy with one or more biopsies must show elevated levels of eosinophils to diagnose EGIDs.

Supplemental criteria rationale - Diagnosis of EGIDs is invasive, expensive, and possesses a risk to the health of the patient. Given the risks, endoscopies are often not ordered by a physician until after many months or years of trying alternatives. Obtaining the diagnosis is a critical first step to obtaining treatment.

<sup>1</sup> Eosinophilic esophagitis: Updated consensus recommendations for children and adults, J Allergy Clin Immunol., Volume 128, Issue 1, Pages 3-20.e6, July 2011.  
<http://www.ncbi.nlm.nih.gov/pubmed/21477849>

### How long does it take to be diagnosed with an Eosinophilic Gastrointestinal Disorder?

An Internet-based survey of self-reported data in 2012 collected by the American Partnership for Eosinophilic Disorders (a national non-profit patient advocacy organization) based on input across the United States, showed that:

- 24% of people were diagnosed within 12 months
- 59% within 24 months
- 15% took more than 10 years.

Seventy-five percent (75%) – a strong majority – took less than 4 years in order to receive a definitive diagnosis.

Supplemental criteria rationale – The diagnosis method for EGIDs is invasive, expensive, and possesses a real health risk to the patient and, as a result, EGID diagnoses often take several years. 60% of people take up to 2 years to get an EGID diagnosis. More often than not, people are misdiagnosed with GERD or food allergies and are not properly diagnosed until they fail to thrive or have a food impaction in their esophagus.

### What age groups are impacted by Eosinophilic Gastrointestinal Disorders?

An Internet-based survey of self-reported data in 2012 collected by the American Partnership for Eosinophilic Disorders, (a national non-profit patient advocacy organization) based on input across the United States, showed that:

- 70% of people diagnosed with EGIDs are age 12 and under
- 12% are age 31 and over

Supplemental Criteria rationale - EGIDs are an inherited chronic disorder that impact people of all ages. Insurance providers should consider coverage for people of all ages for this inherited disorder.

### How long has the patient required medical foods for the treatment of Eosinophilic Gastrointestinal Disorders?

An Internet-based survey of self-reported data in 2012 collected by the American Partnership for Eosinophilic Disorders, (a national non-profit patient advocacy organization) based on input across the United States, showed that:

- 64% of patients only used a medical food for 2 years or less
- 22% using it for less than 6 months
- 19% using medical foods for 5 years or more

Supplemental criteria rationale - As the data above shows, people often need access to medical foods for a brief period to stabilize their gastrointestinal systems in order to build a complete and nutritious diet. Only the most acutely ill of those with EGIDs may require medical food coverage for an extended period of time.

## How long have Eosinophilic Gastrointestinal Disorders been diagnosed?

It is believed that Eosinophilic Gastrointestinal Disorders (EGIDs) were first identified in the 1970's.<sup>1</sup> Insurance codes for EGIDs were not available until the October of 2010. Since then, there has been significant research into the field to help provide better data, enhanced diagnosis and treatment.

Supplemental criteria rationale - This is a newly identified disorder. Based on research cited in section 3 there are scientifically researched and proven treatments for this disorder. Since this disorder is relatively new and there is scientific backing for the treatment, our health care system should consider updating to reflect the need for coverage.

<sup>1</sup> <http://f1000.com/prime/reports/pubmed/20948735>

## How do other states handle Eosinophilic Gastrointestinal Disorders?

There are currently 13 states that have medical food coverage for the treatment and diagnosis of Eosinophilic Gastrointestinal Disorders (EGIDs): Arizona<sup>1</sup>, Connecticut<sup>2</sup>, Illinois<sup>3</sup>, Maine<sup>4</sup>, Maryland<sup>5</sup>, Massachusetts<sup>6</sup>, Minnesota<sup>7</sup>, New Hampshire<sup>8</sup>, New Jersey<sup>9</sup>, New York<sup>10</sup>, Oregon<sup>11</sup>, Rhode Island<sup>12</sup>, and Texas<sup>13</sup>.

There are 14 states seeking coverage or expanded medical food coverage this year – some of which have active legislation in 2013: Connecticut, Florida, Georgia, Louisiana, Massachusetts, Montana, Nebraska, New Mexico, New Jersey, North Carolina, Pennsylvania, Utah, Wisconsin, and Washington State.

Supplemental criteria rationale – We are not the first state considering covering medical foods for EGIDs. Potential learnings, research, and data from other states about the risks and benefits for this benefit should be considered.

<sup>1</sup> <http://www.azleg.gov/legtext/47leg/2r/bills/hb2364h.pdf>

<sup>2</sup> <http://www.cga.ct.gov/2007/ACT/PA/2007PA-00197-R00SB-00066-PA.htm>

<sup>3</sup> <http://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=095-0520&GA=095>

<sup>4</sup> [http://www.mainelegislature.org/legis/bills/bills\\_123rd/chappdfs/PUBLIC595.pdf](http://www.mainelegislature.org/legis/bills/bills_123rd/chappdfs/PUBLIC595.pdf)

<sup>5</sup> <http://mgaleg.maryland.gov/2008rs/bills/hb/hb0578e.pdf>

<sup>6</sup> <http://www.malegislature.gov/Laws/GeneralLaws/PartI/TitleIV/Chapter32a/Section17a>

<sup>6</sup> <http://www.malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter176g/Section4d>

<sup>6</sup> <http://www.malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter176b/Section4k>

<sup>6</sup> <http://www.malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter176a/Section8l>

<sup>6</sup> <http://www.malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section47i>

<sup>7</sup> Minnesota Health Carriers choose to include coverage without a state mandate

<sup>8</sup> <http://www.gencourt.state.nh.us/legislation/1996/hb1431.htm>

<sup>9</sup> [http://www.njleg.state.nj.us/2000/Bills/PL01/361\\_.HTM](http://www.njleg.state.nj.us/2000/Bills/PL01/361_.HTM)

<sup>10</sup>

[http://public.leginfo.state.ny.us/LAWSSEAF.cgi?QUERYTYPE=LAWS+&QUERYDATA=\\$\\$ISC3221\\$\\$@TXISC03221+&LIST=SEA149+&BROWSER=EXPLORER+&TOKEN=57900054+&TARGET=VIEW](http://public.leginfo.state.ny.us/LAWSSEAF.cgi?QUERYTYPE=LAWS+&QUERYDATA=$$ISC3221$$@TXISC03221+&LIST=SEA149+&BROWSER=EXPLORER+&TOKEN=57900054+&TARGET=VIEW)

<sup>11</sup> <http://www.leg.state.or.us/09reg/measpdf/hb3400.dir/hb3496.en.pdf>

<sup>12</sup> <http://www.rilin.state.ri.us/statutes/title27/27-18/27-18-70.htm>

<sup>12</sup> <http://www.rilin.state.ri.us/statutes/title27/27-19/27-19-61.htm>

<sup>12</sup> <http://www.rilin.state.ri.us/statutes/title27/27-20/27-20-56.htm>

<sup>12</sup> <http://www.rilin.state.ri.us/statutes/title27/27-41/27-41-74.htm>

<sup>13</sup> <http://www.legis.state.tx.us/tlodocs/81R/billtext/pdf/HB02000F.pdf#navpanes=0>

## What other disorders may benefit from medical food coverage similar to Eosinophilic Gastrointestinal Disorders?

Washington State has an existing medical food coverage provision (RCW 48.20.520, 48.21.300, 48.44.440, and 48.46.510) which covers people diagnosed with Phenylketonuria (PKU). There are several rare disorders that would benefit from medical food treatments, in addition to Eosinophilic Gastrointestinal Disorders (EGIDs): Food Protein Induced Enterocolitis Syndrome (FPIES), Short Bowel, and other Metabolic Diseases (beyond PKU).

\* Camp KM, Lloyd-Puryear MA, Huntington KL, Nutritional treatment for inborn errors of metabolism: indications, regulations, and availability of medical foods and dietary supplements using phenylketonuria as an example. *Mol Genet Metab.* 2012; 107(1-2):3-9  
<http://www.ncbi.nlm.nih.gov/pubmed/22854513>

\* Belanger-Quintana A, Dokoupil K, Gokmen-Ozel H, et. al. Diet in phenylketonuria: a snapshot of special dietary costs and reimbursement systems in 10 international centers. *Mol Genet Metab.* 2012 Mar;105(3):390-4. doi: 10.1016/j.ymgme.2011.12.004. Epub 2011 Dec 13.  
<http://www.ncbi.nlm.nih.gov/pubmed/22217429>

\* De Greef E, Mahler T, Janssen A, Cuypers H, Veereman-Wauters G, The Influence of Neocate in Paediatric Short Bowel Syndrome on PN Weaning. *Journal of Nutrition and Metabolism* Volume 2010, Article ID 297575, 6 pages  
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2915748/>

\* Weaver, Meredith A. et al. Medical Foods: Inborn Errors of Metabolism and the Reimbursement Dilemma, *Genetics in Medicine*, Vol. 12, No. 6, June 2010, at 365.

<http://www.ncbi.nlm.nih.gov/pubmed/20445457>

\* Byrne, Theresa A. et al., A New Treatment for Patients with Short-Bowel Syndrome: Growth Hormone, Glutamine and a Modified Diet, *Annals of Surgery*, Vol. 222, No.3, at 250.

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1234799/>



# Follow-up to the Sunrise Review: Eosinophilia Gastrointestinal Disorders Mandated Benefit Sunrise

Hearing Date – July 22, 2013

Author: Jeff Schwartz

## Introduction

This document intends to answer some of the questions asked during the Eosinophilic Gastrointestinal Disorder (EGID) Sunrise Review. The focus will be on the access to medical foods and their classification by the Food and Drug Administration (FDA).

Questions answered in this document:

- What are medical foods?
- What foods are designated as a medical food by the FDA?
- What is an elemental formula?
- What is Washington's current mandated coverage for medical food?

## Summary

To summarize, elemental formulas – also known as amino-acid based formulas – are classified as medical foods by the FDA and considered an Orphan Drug. A treatment option for those acutely ill with Eosinophilic Gastrointestinal Disorders is a specially produced medical food produced by Abbott Laboratories, Nutricia Advanced Medical Nutrition, Mead Johnson Nutrition, and Nestle Health Science.

The regulatory supervision for the distribution and manufacturing of medical foods is done by the FDA.

The State of Washington established medical food coverage for the treatment of Phenylketonuria (PKU) in 1988. This statute is narrowly written and as such Washington has not been adversely impacted – as far as I can tell – by the affordances for medical foods provided by the Orphan Drug Act (including over-the-counter access). In Washington medical foods are covered only for patients diagnosed with PKU and only for medical foods that treat PKU.

Similar to PKU, EGID medical food coverage can be narrowly written to only provide medical foods for patients diagnosed with EGIDs and only for medical foods that treat EGIDs.

## What are medical foods?

The FDA has the definitive answer on what constitutes a medical food. Attached to this document are CFR-2001-title21-vol2-part101 and Medical Foods Program – Import and Domestic which contain the definition and the regulatory requirements for medical foods.

The FDA is consistent in its classification of medical foods across the following points:

- Medical foods are specially formulated and processed products (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of patients
- Medical foods must be consumed or administered under the supervision of a physician
- Medical foods may be taken both orally and/or enterally
- Medical foods are Orphan Drugs and as such are afforded special leeway in distribution and regulation to help support research and development where a sufficient profit motivation may not exist

Below are two relevant excerpts from these documents.

### [CFR-2001-title21-vol2-part101](#)

Source: <http://www.gpo.gov/fdsys/pkg/CFR-2001-title21-vol2/pdf/CFR-2001-title21-vol2-part101.pdf>  
(page 34)

Summary: Medical foods classified under the Orphan Drug Act must be consumed or administered under the supervision of a physician, may be taken orally or enterally, and are specially formulated and processed products (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of patients.

#### Excerpt:

(8) Medical foods as defined in section 5(b) of the Orphan Drug Act (21 U.S.C.360ee(b)(3)). A medical food is a food which is formulated to be consumed or administered enterally **under the supervision of a physician** and which is intended for the **specific dietary management of a disease or condition for which distinctive nutritional requirements**, based on recognized scientific principles, are established by medical evaluation. A food is subject to this exemption only if:

(i) **It is a specially formulated and processed product** (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of **oral intake or enteral feeding by tube**;

(ii) It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;

(iii) It provides nutritional support specifically modified for the management of the **unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation**;

(iv) **It is intended to be used under medical supervision**; and

(v) **It is intended only for a patient receiving active and ongoing medical supervision** wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

## Medical Foods Program – Import and Domestic

Source: <http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm073339.pdf>

Summary: The Medical Foods coding 41G is for foods that are specially formulated and processed for the patient who is seriously ill or requires the product as a major treatment modality. Given the critical need for safe medical foods the FDA is committed to assuring their continued safety and integrity through annual inspections of all medical foods manufacturers in the U.S. and foreign countries.

### Excerpt:

The term "medical food" is defined in the Orphan Drug Act Amendments of 1988 [21 USC 360ee (b)(3)]. This definition was incorporated by reference into the Nutrition Labeling and Education Act (P.L. 101-535) in November 1990. It is incorporated into the agency's final rule on mandatory nutrition labeling published in January 1993. \*The definition of a medical food is a food which is formulated to be consumed or administered enterally **under the supervision of a physician** and which is **intended for the dietary management of a specific disease or condition** for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. (See 21 CFR 101.9(j)(8)).\*

Generally, to be considered a medical food, a product must, at a minimum, meet the following criteria:

- a) The product is a food for **oral or tube feeding**;
- b) The product is labeled for the **dietary management of a medical disorder, disease, or condition**; and
- c) The product is labeled to be used **under medical supervision**, and is **primarily obtained through hospitals, clinics, and other medical and long term care facilities**.

**Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods are to be used under medical supervision.** The term "medical foods" does not pertain to all foods fed to sick patients. **Medical foods are foods that are specially formulated and processed** (as opposed to a naturally occurring foodstuff used in its natural state) for the patient who is seriously ill or who requires the product as a major treatment modality. Typical medical foods are enteral nutrition products, i.e., products provided through the gastrointestinal tract, taken by mouth, or provided through a tube or catheter that delivers nutrients beyond the oral cavity or directly to the stomach.

...

Because of the susceptible population for which medical foods are intended, the agency is committed to assuring their continued safety and integrity through annual inspections of all medical foods manufacturers in the U.S. and foreign countries.

...

The following new product codes have been established and are currently in effect for coding medical foods.

Industry 41—Dietary Conventional Foods and Meal Replacements

41G Medical Foods (foods that are specially formulated and processed for the patient who is seriously ill or requires the product as a major treatment modality)

## Orphan Drug Act

Source: <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/SignificantAmendmentstotheFDCAAct/OrphanDrugAct/default.htm>

Summary: Orphan Drugs Act was established to reduce the costs of developing such drugs and to provide financial incentives to develop such drugs.

### Excerpt:

Orphan Drug Act – Excerpts (Public Law 97-414, as amended)

#### CONGRESSIONAL FINDINGS FOR THE ORPHAN DRUG ACT

The Congress finds that---

(1) there are many diseases and conditions, such as Huntington's disease, myoclonus, ALS (Lou Gehrig's disease), Tourette syndrome, and muscular dystrophy which **affect such small numbers of individuals residing in the United States** that the diseases and conditions are considered rare in the United States;

(2) adequate drugs for many of such diseases and conditions have not been developed;

(3) **drugs for these diseases and conditions are commonly referred to as "orphan drugs";**

(4) because so few individuals are affected by any one rare disease or condition, a pharmaceutical company which develops an orphan drug may reasonably expect the drug to generate relatively small sales in comparison to the cost of developing the drug and consequently to incur a financial loss;

(5) there is reason to believe that some promising orphan drugs will not be developed unless changes are made in the applicable Federal laws to reduce the costs of developing such drugs and **to provide financial incentives to develop such drugs;** and

(6) **it is in the public interest to provide such changes and incentives for the development of orphan drugs.**

## What foods are designated as a medical food by the FDA?

I was not able to find a recent list medical foods, as classified by the FDA. I believe this is a proprietary list maintained by the FDA which is not shared with the public. As potential evidence of this, the Medical Food Compliance Enforcement document had 2 attachments which were both removed before publishing publicly stating they are 'not for public distribution'.

<http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm073339.pdf>

Attachment A--List of known foreign medical foods manufacturers/shippers and their products  
**(Not for Public Distribution)**



## What is Washington’s current mandated coverage for medical food?

The State of Washington currently mandates coverage for medical foods for the treatment of Phenylketonuria (PKU).

Critical note – The treatments for PKU and EGIDs are different and I am not trying to equate the disorders, though the treatment for PKU and EGIDs both benefit from medical foods, so there is a potential corollary in how to effectively mandate coverage for medical foods.

RCW 48.20.520, 48.21.300, 48.44.440, and 48.46.510 establish coverage for medical foods for the treatment of PKU: established in 1988.

- <http://apps.leg.wa.gov/RCW/default.aspx?cite=48.20.520>
- <http://apps.leg.wa.gov/RCW/default.aspx?cite=48.21.300>
- <http://apps.leg.wa.gov/RCW/default.aspx?cite=48.44.440>
- <http://apps.leg.wa.gov/RCW/default.aspx?cite=48.46.510>

Based on a document by Mead Johnson Nutrition ([http://www.meadjohnson.com/documents/specialized\\_feeding\\_solutions\\_fact\\_sheet.pdf](http://www.meadjohnson.com/documents/specialized_feeding_solutions_fact_sheet.pdf)), who manufactures a small number of products that treat metabolic disorders like PKU, these medical foods are granted the same affordances by the FDA as would medical foods used for the treatment of EGIDs. A concrete example that was brought up at the Sunrise Review hearing is that these medical foods are also available over the counter (OTC) as are all medical foods. An internet search for ‘Phenyl Free 1’ showed that it could be purchased online – though like all medical foods, it is explicitly formulated to be administered under the supervision of a physician.

# Appendix B

## Proposed Bill





CERTIFICATION OF ENROLLMENT

**SUBSTITUTE HOUSE BILL 1216**

Chapter 168, Laws of 2013

63rd Legislature  
2013 Regular Session

INSURANCE--EOSINOPHILIA GASTROINTESTINAL ASSOCIATED DISORDERS

EFFECTIVE DATE: 07/28/13

Passed by the House April 18, 2013  
Yeas 89 Nays 5

FRANK CHOPP

\_\_\_\_\_  
**Speaker of the House of Representatives**

Passed by the Senate April 12, 2013  
Yeas 46 Nays 0

BRAD OWEN

\_\_\_\_\_  
**President of the Senate**

Approved May 8, 2013, 2:14 p.m.

JAY INSLEE

\_\_\_\_\_  
**Governor of the State of Washington**

CERTIFICATE

I, Barbara Baker, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is **SUBSTITUTE HOUSE BILL 1216** as passed by the House of Representatives and the Senate on the dates hereon set forth.

BARBARA BAKER

\_\_\_\_\_  
**Chief Clerk**

FILED

May 8, 2013

**Secretary of State  
State of Washington**

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**SUBSTITUTE HOUSE BILL 1216**

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AS AMENDED BY THE SENATE

Passed Legislature - 2013 Regular Session

**State of Washington                      63rd Legislature                      2013 Regular Session**

**By** House Health Care & Wellness (originally sponsored by Representatives Habib, Clibborn, Jenkins, McCoy, Springer, Morrell, Goodman, Appleton, Tarleton, Ryu, Tharinger, and Fey)

READ FIRST TIME 02/12/13.

1            AN ACT Relating to eosinophilia gastrointestinal associated  
2 disorders; and creating new sections.

3 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

4            NEW SECTION.    **Sec. 1.** The department of health shall, using the  
5 procedures and standards set forth in chapter 48.47 RCW, conduct a  
6 sunrise review of the proposal, as set forth in House Bill No. 1216  
7 (2013), requiring health carriers to include formulas necessary for the  
8 treatment of eosinophilia gastrointestinal associated disorders,  
9 regardless of the delivery method of the formula. The department shall  
10 report the results of the review no later than thirty days prior to the  
11 2014 legislative session.

12           NEW SECTION.    **Sec. 2.** Each carrier shall continue to apply a  
13 timely appeals and grievance process as outlined in RCW 48.43.530 to  
14 ensure medically necessary treatment is available. Expedited appeals  
15 must be completed when a delay in the appeal process could jeopardize  
16 the enrollees' life, health, or ability to regain maximum function.

          Passed by the House April 18, 2013.

          Passed by the Senate April 12, 2013.

          Approved by the Governor May 8, 2013.

          Filed in Office of Secretary of State May 8, 2013.

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HOUSE BILL 1216

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State of Washington

63rd Legislature

2013 Regular Session

By Representatives Habib, Clibborn, Jinkins, McCoy, Springer, Morrell, Goodman, Appleton, Tarleton, Ryu, Tharinger, and Fey

Read first time 01/21/13. Referred to Committee on Health Care & Wellness.

1 AN ACT Relating to eosinophilia gastrointestinal associated  
2 disorders; and amending RCW 48.20.520, 48.21.300, 48.44.440, and  
3 48.46.510.

4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

5 **Sec. 1.** RCW 48.20.520 and 1988 c 173 s 1 are each amended to read  
6 as follows:

7 ~~((1) The legislature finds that:~~

8 ~~(a) Phenylketonuria is a rare inherited genetic disorder.~~

9 ~~(b) Children with phenylketonuria are unable to metabolize an~~  
10 ~~essential amino acid, phenylalanine, which is found in the proteins of~~  
11 ~~most food.~~

12 ~~(c) To remain healthy, children with phenylketonuria must maintain~~  
13 ~~a strict diet and ingest a mineral and vitamin-enriched formula.~~

14 ~~(d) Children who do not maintain their diets with the formula~~  
15 ~~acquire severe mental and physical difficulties.~~

16 ~~(e) Originally, the formulas were listed as prescription drugs but~~  
17 ~~were reclassified as medical foods to increase their availability.~~

18 ~~(2))~~ Subject to requirements and exceptions which may be  
19 established by rules adopted by the commissioner, any disability

1 insurance contract delivered or issued for delivery or renewed in this  
2 state on or after September 1, 1988, that insures for hospital or  
3 medical expenses shall provide coverage for the formulas necessary for  
4 the treatment of phenylketonuria. Contracts issued or renewed on or  
5 after January 1, 2016, or upon the earliest update of the benchmark  
6 plan, as defined in RCW 48.43.715 shall include formulas necessary for  
7 the treatment of eosinophilia gastrointestinal associated disorders,  
8 regardless of the delivery method of the formula.

9 **Sec. 2.** RCW 48.21.300 and 1988 c 173 s 2 are each amended to read  
10 as follows:

- 11 ~~((1) The legislature finds that:~~
- 12 ~~(a) Phenylketonuria is a rare inherited genetic disorder.~~
- 13 ~~(b) Children with phenylketonuria are unable to metabolize an~~  
14 ~~essential amino acid, phenylalanine, which is found in the proteins of~~  
15 ~~most food.~~
- 16 ~~(c) To remain healthy, children with phenylketonuria must maintain~~  
17 ~~a strict diet and ingest a mineral and vitamin enriched formula.~~
- 18 ~~(d) Children who do not maintain their diets with the formula~~  
19 ~~acquire severe mental and physical difficulties.~~
- 20 ~~(e) Originally, the formulas were listed as prescription drugs but~~  
21 ~~were reclassified as medical foods to increase their availability.~~
- 22 ~~(2)) Subject to requirements and exceptions which may be~~  
23 ~~established by rules adopted by the commissioner, any group disability~~  
24 ~~insurance contract delivered or issued for delivery or renewed in this~~  
25 ~~state on or after September 1, 1988, that insures for hospital or~~  
26 ~~medical expenses shall provide coverage for the formulas necessary for~~  
27 ~~the treatment of phenylketonuria. Contracts issued or renewed on or~~  
28 ~~after January 1, 2016, or upon the earliest update of the benchmark~~  
29 ~~plan, as defined in RCW 48.43.715 shall include formulas necessary for~~  
30 ~~the treatment of eosinophilia gastrointestinal associated disorders,~~  
31 ~~regardless of the delivery method of the formula.~~

32 **Sec. 3.** RCW 48.44.440 and 1988 c 173 s 3 are each amended to read  
33 as follows:

- 34 ~~((1) The legislature finds that:~~
- 35 ~~(a) Phenylketonuria is a rare inherited genetic disorder.~~

1       ~~(b) Children with phenylketonuria are unable to metabolize an~~  
2 ~~essential amino acid, phenylalanine, which is found in the proteins of~~  
3 ~~most food.~~

4       ~~(c) To remain healthy, children with phenylketonuria must maintain~~  
5 ~~a strict diet and ingest a mineral and vitamin enriched formula.~~

6       ~~(d) Children who do not maintain their diets with the formula~~  
7 ~~acquire severe mental and physical difficulties.~~

8       ~~(e) Originally, the formulas were listed as prescription drugs but~~  
9 ~~were reclassified as medical foods to increase their availability.~~

10       ~~(2)) Subject to requirements and exceptions which may be~~  
11 ~~established by rules adopted by the commissioner, any contract for~~  
12 ~~health care services delivered or issued for delivery or renewed in~~  
13 ~~this state on or after September 1, 1988, shall provide coverage for~~  
14 ~~the formulas necessary for the treatment of phenylketonuria. Contracts~~  
15 ~~issued or renewed on or after January 1, 2016, or upon the earliest~~  
16 ~~update of the benchmark plan, as defined in RCW 48.43.715 shall include~~  
17 ~~formulas necessary for the treatment of eosinophilia gastrointestinal~~  
18 ~~associated disorders, regardless of the delivery method of the formula.~~

19       **Sec. 4.** RCW 48.46.510 and 1988 c 173 s 4 are each amended to read  
20 as follows:

21       ~~(1) ((The legislature finds that:~~

22       ~~(a) Phenylketonuria is a rare inherited genetic disorder.~~

23       ~~(b) Children with phenylketonuria are unable to metabolize an~~  
24 ~~essential amino acid, phenylalanine, which is found in the proteins of~~  
25 ~~most food.~~

26       ~~(c) To remain healthy, children with phenylketonuria must maintain~~  
27 ~~a strict diet and ingest a mineral and vitamin enriched formula.~~

28       ~~(d) Children who do not maintain their diets with the formula~~  
29 ~~acquire severe mental and physical difficulties.~~

30       ~~(e) Originally, the formulas were listed as prescription drugs but~~  
31 ~~were reclassified as medical foods to increase their availability.~~

32       ~~(2)) Subject to requirements and exceptions which may be~~  
33 ~~established by rules adopted by the commissioner, any agreement for~~  
34 ~~health care services delivered or issued for delivery or renewed in~~  
35 ~~this state on or after September 1, 1988, shall provide coverage for~~  
36 ~~the formulas necessary for the treatment of phenylketonuria. Contracts~~  
37 ~~issued or renewed on or after January 1, 2016, or upon the earliest~~

1 update of the benchmark plan, as defined in RCW 48.43.715 shall include  
2 formulas necessary for the treatment of eosinophilia gastrointestinal  
3 associated disorders, regardless of the delivery method of the formula.  
4 (2) Such formulas shall be covered when deemed medically necessary  
5 by the medical director or his or her designee of the health  
6 maintenance organization and if provided by the health maintenance  
7 organization or upon the health maintenance organization's referral.  
8 Formulas shall be covered at the usual and customary rates for such  
9 formulas, subject to contract provisions with respect to deductible  
10 amounts or co-payments.

--- END ---

# Appendix C

## Follow Up to Applicant Report





Eosinophilia Gastrointestinal Associated Disorders (EGIDs)  
Mandated Benefit Sunrise Follow Up Questions to Applicant  
June 10, 2013  
Reply – July 17, 2013

**Social Impact**

1. In question (1)(i) you provide information from Option 1 Nutrition Solutions on the percentage of their business in Washington on medical foods, those diagnosed with an EGID, and drinking versus enteral administration.

**Can you provide actual numbers to accompany these percentages?**

Option 1 Nutrition Solutions is a private company that provided statistical data about their enteral coverage across 4 states: WA, AZ, CO, and OR. As a private company they felt that providing actual numbers may put their company at a competitive disadvantage and as such did not provide them. I am grateful for the support from Option 1 Nutrition Solutions in providing the information they felt comfortable with providing.

2. In question (1)(i) you request our assistance in obtaining data on people in Washington diagnosed with EGIDs.

**We are attempting to obtain this data for government plans such as Medicaid, WSHIP, and PEB. However, we cannot help with this data for non-government plans, such as Asuris Health. You will most likely need to contact these carriers directly to access this information.**

As you can imagine, acquiring this information as a non-member is a next to impossible task due to the proprietary nature of this information. Examples of difficulties include: A) 1-800 numbers only provide service during business hours, B) connecting with the carrier's medical director, and, C) successfully obtaining the above information from the medical director.

In our current system this information is proprietary to each individual carrier. At this point I do not have any data to provide.

By asking the DOH/OIC for this information I hoped that the above information could be retrieved using the preexisting professional relationships with the carriers.

3. In question (1)(ii) you request our assistance in obtaining information, specifically on "What section of the WA health policies offer coverage for medical food Does this explicitly include coverage for EGIDs? Is the coverage for enteral, oral, or both?"

**We are attempting to obtain this information for government plans such as Medicaid, WSHIP, and PEB. However, we cannot help with information for non-**

**government plans. You will most likely need to contact these carriers directly to access this information.**

Same reply as #2.

### **Financial Impact**

4. In (2)(i) you provide a cost estimate of \$5,000 for a hospital stay when a patient isn't receiving adequate treatment. In (2)(iii) you state that oral feeding is more cost effective than enteral administration.

**Can you provide a comparison between oral and enteral administration of elemental formulas?**

Costs for the treatment of Eosinophilic Gastrointestinal Disorders are tailored to individual patient and their insurance carrier. I asked some of the families in Washington State what they are billed for maintaining a feeding tube, below is their experience.

The same medical food is used both enterally and orally treatment – as a result, the base cost is the same: \$1,000-\$1,500 a month.

Having a Gastrostomy feeding tube (G-Tube) has additional expenses:

- Tube supplies: \$1,000 a month
- Tube adjustments (surgical): >\$1,000 (as frequent as every 3-6 months)
- Pump rental: \$300+ a month
- Tube installation (surgical): >\$1,000

There are other aspects to being tube feed that need to be considered. G-Tubes do not grow with the patient and as such need to be replaced to accommodate growth. Additional support staff – like live-in nurses – may be required in the home to support night time feedings or the maintenance and care of the feeding tube.

In addition to the cost aspects of having a feeding tube there are often physical and social impacts to having a feeding tube. These range from having to explain the tube extending from your nose to your back-pack, or the lump under your shirt for your g-tube, to physical imitations of just not being able to keep up (due to fatigue) or unable to participate due to tenderness or risk of injury or damage to the feeding tube site.

On average the cost of being tube feed is 3 to 4 times more expensive than being fed orally.

5. You indicate in question (2)(iii) that oral administration of elemental formulas would be a substitute for the more expensive enteral administration. However, you indicate in (1) (ii) that you do not expect coverage of oral formulas to increase the use of oral treatment.

**Is there any indication that patients who are candidates for oral formula are being put on enteral administration because enteral is covered and oral is not?**

The sad answer is yes – though I do not know of any families in Washington State that chose a feeding tube just because of insurance coverage.

To help provide an answer I posted this question on multiple support groups for Eosinophilic Gastrointestinal Disorders. Below I provide two of the replies (provided anonymously) – use these as a glimpse into the decision matrix patients and their parents used to make the decision to be tube fed.

“Our primary insurance still does not cover it [medical food taken orally]. And the state Medicaid covers it with a tube. We chose a tube because our son would not drink the formula. At the time we did not consider insurance. But a plus now.”

“One of the reasons we chose [a] tube is because [it was] only covered if via tube, it's not the only reason”

Medical foods used in the treatment of Eosinophilic Gastrointestinal Disorders taste disgusting (barely palatable), to put it mildly. These medical foods are – in essence – pre-digested food proteins broken down into amino-acids (which are the basic building blocks of everything). They taste so bad because there is no way to mask the flavor of these amino-acids because these medical foods have to be none-allergic, so sugar and natural flavors are not appropriate taste maskers. The result is a medical food that provides nutrition but is barely palatable which causes a struggle to drink enough required for daily nutrition.

An Internet-based survey of self-reported data in 2012 collected by the American Partnership for Eosinophilic Disorders (a national non-profit patient advocacy organization) based on input across the United States, showed that: 39.4% of patients dealing with Eosinophilic Gastrointestinal Disorders are under the age of 5. Speaking generally, children under the age of 5 care deeply about what they eat (and can be picky eaters) and can be very stubborn (they may choose to go hungry as opposed to eat what you offer them). This combination is both frustrating and potentially harmful for the patient if they are unable to drink the elemental formula.

Speaking personally, when our insurance carrier dropped our coverage we spent months researching and debating requesting a feeding tube from our doctor – it was not a decision we would make lightly. We were fortunate that Jacob drank this medical food from 6 months until 3 ½ through a baby bottle – which would shoot the liquid to the back of his throat there by reducing the chance he needed to taste it. We knew that bottles were not a long term path for his nutritional needs and tried relentlessly to transition to a sippy-cup, with no luck. If we had to remain on Elecare long term we would have likely

had to explore a feeding tube, not only because of the lack of insurance coverage but because Jacob would not be able to drink enough calories to remain healthy.

# Appendix D

## Written Comments



Eosinophilic Gastrointestinal Associated Disorders (EGID)  
Mandated Benefit Sunrise Review  
Public Comments Received  
July 29, 2013

Our seven-year old son cannot eat due to having an eosinophilic disorder. We went to Children's Hospital of Philadelphia, where we received his diagnoses and treatment plan. So, on top of paying \$22,000. a year currently for our health insurance (we are self-employed), and all the various out-of-pocket co-pays, the insurance company refuses to cover this special elemental formula that sustains his life. We currently pay approx. \$14,000. a year just for his formula (Neocate Jr.). Kind of makes having insurance for major illness/chronic illness a joke.

Please change the law, so these formulas are covered for eosinophilic disorders (whether fed through a tube or taken orally).  
Thank you, Ellen Lepping

---

Hello. I am the mother of a 9 year old boy with Eosinophilic Esophagitis. Some of his white blood cells (eosinophils) mistakenly attack his food pathway in his throat (esophagus). It's just like asthma, only the inflammation, damage and mucus are happening in his food pathway instead of his airways. This makes food and eating a problem for Nicolas. He has tried both of the (only two) accepted medicines for this disease and we haven't yet gotten his symptoms under control. He's always been thin, but recently he's been losing weight. If this continues, his only option will be Elemental Formula, which is broken down into amino acids so there are no pesky proteins to set off the inflammation. As difficult as it is for a 9 year old to go without completely food, we are glad that there is a way to left to help him. Aside from the fact that he will probably have to have feedings through a Nasogastric tube, or a direct shunt, Gastric tube into his belly because the formulas taste so bad even hungry kids can't bring themselves to swallow enough for adequate calories, the cost is phenomenal. At our local WalMart pharmacy the price is \$35 a single serving can. Our son would need 8 of these every day to live. Though we have found an online source for about \$100 a day with a different formula. Of course we may not get to pick. We would have to give our son whatever the doctor prescribes. Please help other families affected by Eosinophilic disorders by covering the high cost of prescription nutrition, under healthcare as it's necessary to life. Thank you,  
Maria Urton

---

Patients of Eosinophilic disorders are truly victims. They have lost one of their primary, necessary, enjoyments in life, the sheer ability to just eat. I not only agree, but plead, that you cover the cost of food for people who suffer from Eosinophilic disorders under their insurances.

My son, who is 24-years-old, suffers from Eosinophilic Esophagitis among other things. His food bills, combined with his medical bills and basic care, are staggering. This disorder is entirely about food, and the human body's ability to merely survive. We need help financially.

1. This is not just a Washington issue, there is a nationwide need for this coverage.
2. Potential necessary financial assistance through non-profits for victims of Eosinophilic

Disorders, are primarily geared toward children, meaning my son is too old.

3. The states vary on the way they handle disability which can prevent victims from getting basic financial support they need. Due to my son's age, he was denied State Disability, because--due to being in college--he had not worked in the year prior to his EoE triggering--so he didn't qualify. The State denied him even though he spent EVERYDAY for seven months of the year in the emergency room, admitted in the hospital, in doctor's offices, or in urgent care.
2. The medical costs alone involved in having a Eosinophilic disorder is staggering, let alone the expense food and food trials.
3. Determining what foods a person can tolerate is a lifelong, expensive, hit and miss process. Allergy/sensitivity testing for Eosinophilic disorders has not been perfected, and "most" of the results are hit and miss.
5. Oftentimes, testing a new food results in an emergency room visit, caused entirely by the food/ingredients itself.
6. Eosinophilic disorder reactions can also be caused by food dyes, food additives, etc. which are already known to be bad for human health. In a healthy person, these items can be bad; however, for an Eosinophilic person they can literally be life or death.
7. Feeding tube food/products also need to be covered under insurances. Many victims of Eosinophilic disorders are forced to be on a feeding tube for the rest of their lives. In addition, my son also suffers from Type 1 Diabetes (due to blunt force trauma). There needs to be grant money made available for people to develop:
  - A. Additional low-sugar feeding tube products, and
  - B. Feeding tube products which contain only one or two ingredients in them--with no chemicals or food additives. Most Eosinophilic victims can only tolerate an extremely limited, specific type of food. There are currently NO feeding tube products for my son, who suffers from Eosinophilic Esophaguitis and Diabetes (everything has to be handmade at the risk of contamination),
  - C. Medicines (e.g. insulins), personal hygiene products, TPN, etc. which do not contain phenol and other toxic chemicals, dyes, etc..
  - D. Regular food products containing less than three ingredients without any additives.
8. In addition, as a side note, all medications available to treat Eosinophilic disorders need to be covered, even experimental drugs or those approved for use by other countries. My son to merely survive takes Cromolyn (developed in the U.S., approved in Canada) daily, which is the third most expensive drug in the world. Other patients medical insurance will not cover the cost of this drug. Also, Eosinophilic disorders need to be added to Social Securities list of automatically approved benefit list due to its debilitating nature.
9. Foods we have been extremely fortunate to find my son can tolerate are basically organic and expensive. He currently can tolerate: Organic chicken; quinoa; green beans and corn packed only in water; organic cranberries lemons and limes, and bottled Arrowhead water. Since he is diabetic, corn and cranberries--due to the sugar content--have to be very limited.

Sincerely, C. Nickel, California Resident

---

We recommend that the word "elemental" be added in front of the word "formula" in order to prevent any confusion and make the law more specific.

Kate Romanow, Regence BlueShield, Regulatory Administrator



July 8, 2013

Sherry Thomas  
Washington State Department of Health  
P.O. Box 47850  
Olympia, WA 98504-7850

RE: Mandated Benefit Sunrise Review – Insurance Coverage of Treatment of Eosinophilia  
Gastrointestinal Associated Disorders

Dear Ms. Thomas,

On behalf of Premera Blue Cross, thank you for the opportunity to provide comments regarding the mandated benefit sunrise review of insurance coverage for treatment of eosinophilia gastrointestinal associated disorders (EGIDs).

We recognize the importance of providing coverage for individuals who are diagnosed with EGIDs. Premera currently provides coverage for medically necessary enteral nutritional support via a feeding tube for patients who are diagnosed with certain conditions. Coverage for enteral nutritional support is predicated on the patient needing a specific medical intervention, such as a feeding tube, to obtain nutrition.

We oppose the proposal to mandate coverage for formulas for the treatment of EGIDs regardless of delivery method. We believe this proposal will be considered a new mandate which may increase costs to the state.

The U.S. Department of Health and Human Services (HHS) has clarified that any state-mandated benefit enacted after December 31, 2011 would not be part of the essential health benefits (EHB) for 2014 and 2015, followed by a review of the EHB policy. Unless federal law is changed commencing in 2016, the state will be obligated to pay the costs of this benefit for any individual receiving subsidies under the Affordable Care Act. To avoid the risk of these costs to the state, we believe the Department of Health (DOH) should wait for the clarification on the federal EHB benchmark plan.

This proposal would also require health insurance policies to cover formulas/supplements which are readily available over-the-counter including through websites such as amazon or ebay. In general, health insurance policies do not cover treatments and items that are available over-the-counter. However, these formulas could well be a qualified medical expense as a nutritional supplement and reimbursable through a Health Savings Account or Health Flexible Spending Account. This provides an option for families to help pay for the cost of the over-the-counter treatment. We are concerned that mandating coverage for these non-prescription items could

lead to an increased number of mandates for other types of nutritional or dietary supplements or foods which are usually not covered under insurance policies.

In conclusion, we do not support this mandate, and we urge the DOH to consider forthcoming federal rules and guidance before taking action. We recognize the financial constraints of families with children affected by EGIDs, but must balance this with the overall impact on premiums from mandated benefits and increased costs to the state of Washington. The cumulative impact of mandated benefits increases the cost of coverage which disproportionately impacts individual and small employer purchasers.

Thank you for the opportunity to offer comments on this proposal.

Sincerely,

A handwritten signature in black ink, appearing to read 'Leonard Sorrin', with a long horizontal flourish extending to the right.

Leonard Sorrin

Vice-President

Congressional and Legislative Affairs



STATE OF WASHINGTON  
**HEALTH CARE AUTHORITY**  
626 8<sup>th</sup> Avenue, S.E. • P.O. Box 45502 • Olympia, Washington 98504-5502

**Memorandum**

To: Sherry Thomas, Policy Coordinator, Health Systems Quality Assurance, Department of Health  
From: Dennis Martin, Administrator, Office of Legislative Affairs and Analysis, Health Care Authority  
Re: Sunrise Review – Insurance Coverage of Treatment of Eosinophilia Gastrointestinal Associate Disorders  
Date: July 10, 2013

Thank you for providing notice of the Sunrise Review hearing regarding insurance coverage of treatment of eosinophilia gastrointestinal associate disorders (EGID). After reviewing the applicant report and proposed legislation, the Washington State Health Care Authority (HCA) submits the following information regarding the benefit plans administered by the HCA that could be affected by this proposed mandate.

Medicaid, Basic Health and the self-funded PEBB plans administered by the Health Care Authority are not impacted by the proposed mandate under Title 48, the insurance code. However, the Medicaid fee-for-service plans already cover the formulas for clients under age 21.

The PEBB self-funded plans currently cover those formulas mandated for PKU and those delivered parentally. These are covered under the durable medical equipment and supplies (DME) benefit. We have no indication that these plans include patients with EGID diagnoses.

The PEBB insured managed care health plans would be impacted by this proposed mandate. Currently the PEBB Kaiser plan covers enteral supplements and formula is elemental formula (Ensure or Elemental Enteral Formula) under the durable medical equipment and supply benefit. Their standard contract language under Covered Drugs, Supplies, and Supplements includes the following definition:

"Medical foods and formulas necessary for the treatment of phenylketonuria (PKU), severe intestinal malabsorption, specified inborn errors of metabolism or other metabolic disorders".

Kaiser pharmacy benefits for this condition are also available. They indicated that this condition is typically treated with specialized enteral (oral) formulas. Their pharmacy only dispenses parenteral formulas which are administered IV and dispensed through their home infusion pharmacy. Enteral formulas are typically given orally or through a feeding tube. They are currently covered under DME (as referenced above).

Group Health indicates that they currently cover the elemental formulas. They do not specify mode of entry into the body, oral or feeding tube. The mandate could result in broadening their list of covered conditions to specify this diagnosis to their list of covered indications. They did not supply the number of current patients, but stated that they are currently paying out approximately \$2,000 annually for each patient utilizing this elemental formula benefit. There is no indication that any PEBB members are affected.

The HCA fiscal impact remains as stated during the past legislative session: No Impact. The health plans affected by this proposed mandate indicate few if any changes would be required to the scope of their current coverage and the conditions are rare, creating a very limited potential for HCA cost impacts.



# Appendix E

## Public Hearing Transcript



Eosinophilic Gastrointestinal Associated Disorders Sunrise  
Public Hearing Transcript  
July 11, 2013

Sherry Thomas, Sunrise Review Coordinator at the Department of Health, Health Systems Quality Assurance Division welcomed everyone to the hearing. Ms. Thomas explained how the hearing would work and gave instructions for public testimony. She explained that the hearing was being recorded so the department can share the recording with people who weren't able to attend.

Next, Ms. Thomas introduced the hearing panel and explained that the panel members responsibility was to ask questions to make sure the department has all the information needed to make a sound recommendation.

- Jennifer Santiago, program manager within the Health Systems Quality Assurance Division at the Department of Health;
- Leslie Magby, compliance officer in the same division;
- Tara Wolff, policy advisor to the state Board of Health.

Ms. Thomas then explained that the department expects the report that will include staff recommendations based in part on the public hearing to go to the secretary of health in October for approval. Then it will go to the legislature by the 1<sup>st</sup> of December. She explained that the hearing was for proponents to make their presentations and for opponents and other interested parties to comment on the proposal. Panel members and department staff would ask questions of the proponent and also of public members who testify.

There will be a 14-day written comment period after the hearing to provide additional information, respond to questions, or to address something said at the hearing. Participants were reminded to keep in mind during presentations and written submissions that there are statutory criteria for the sunrise process. Ms. Thomas stated that this is not a legislative hearing; political arguments or other factors not included in the criteria the legislature has provided will not help or hurt the proposal under review. That is the legislature's job to take those into account.

Next Ms. Thomas introduced Jeff Schwartz and Dr. Uma Pisharody to present the proposal. The panel members were invited to ask questions during their presentation.

**JEFF SCHWARTZ:**

Good morning. I first want to thank you for the opportunity to speak in front of you today. I want to clarify the reasons why Eosinophilic Gastrointestinal Disorders need increased coverage in our state. I am Jeff Schwartz. My son, Jacob, was diagnosed with Eosinophilic Gastritis at six months, which is why I am here today. I would also like to introduce Dr. Uma Pisharody, a pediatric gastroenterologist specialist at Swedish Hospital. So today's presentation...you guys are kind of awkwardly situated (laughter) All right, most of it will be on the screen. Today we are going to...Dr. Pisharody is going to walk through kind of an overview of EGID is. We are going to talk a little bit about the current state of affairs in Washington State are. I'm going to

give a proposed path ahead for us and then I'll wrap up with some final thoughts. Before we get started, I just wanted to up-front say the thing that I believe we really need in this state which is insurance coverage for the treatment and diagnosis of Eosinophilic Gastrointestinal Disorders regardless of delivery method, both enteral and oral, and regardless of age. So with that I'm going to pass it off to Dr. Pisharody and she can take it from there.

**DR. UMA PISHARODY:** So again, from me also, thank you very much for allowing us to provide you with information. I am a board certified pediatrician and pediatric gastroenterologist and my practice, as Jeff mentioned, is at Swedish Medical Center in Seattle. Myself and my partner, we have at least, you know, several dozen patients with this and so we feel that we have the expertise to answer any questions if you want just on the background of this condition. It's not very well known and most patients that we make this diagnosis in say that they have never heard of it and it takes a lot of explaining so that's what I hope to do in maybe five or 10 minutes, just explain what is an eosinophil and what is an Eosinophilic GI disorder.

So eosinophils, which is the reason for this whole disorder, is basically a white blood cell that looks red and so it is shown on this screen here, that is the large white blood cell but, you notice, it is actually the same color as the red blood cells that are surrounding it. So blood obviously has two cells: red blood cells and white blood cells. The white blood cell looks very red because of its acidic granules inside which are the granules that hold all the proteins and molecules that make this cell do what it does, is the eosinophils. You can see that it is three nucleus and all the red granules. That is what an eosinophil is and that is the reason for this whole condition. So they are basically white blood cells who circulate, they circulate normally in the peripheral circulation in the blood, and they get attracted to the lining of the intestinal tract when they sense that something harmful is coming at them. So in presence of any toxin or irritation or infection or anything that they deem harmful, these cells leave our peripheral blood circulation and attack the lining of the GI tract. So in the case of Eosinophilic GI disorders or EGID for short, basically it's food that is the toxic substance. So, as Jeff wrote, you know, very nicely here, food is the dangerous substance or food is the poison for people who have EGIDs. For some reason, food itself is being targeted as a toxin or a foreign substance and the eosinophils are infiltrating and attacking our own GI tract. They have...these eosinophil GI disorders have different names and connotations and so this leads to some confusion, but, basically, it's all one disease and whether or not your esophagus or food pipe is effected, or your stomach or your small intestine or your colon is effected, you can call it different things but it's basically an EGID and it's the same cause for everybody and basically the same treatment for everybody. And so in the case of the upper GI tract, for instance, what we do is we examine the upper GI tract which includes the esophagus, the stomach and the small intestine, then we take...really the diagnostic part of this is taking the biopsies. So it is not really what you see with your naked eye, it's what shows up in those biopsies and that's tons and tons of these eosinophils. You see how red the slide is under the microscope and all these little tiny little individual red cells, those are eosinophils. There are parts of your GI tract where you are not even supposed to have one eosinophil; for instance, the food pipe. Not even one eosinophil is normally found there and in kids with this or adults with this, you just see clusters and clusters of eosinophils. So you know something is targeting these cells to infiltrate that lining.



How do you make the diagnosis? You have to have a high index of suspicion, or low threshold to even think about this. Symptoms are very non-specific like a child who complains of belly pain or a child who complains of not feeling hungry or feeling full too fast or a child who complains of like heart burn or even acid reflux kind of symptoms. So it takes a while sometimes to get to the diagnosis because they are very non-specific symptoms that one pediatrician who has never heard of this might call reflux or just gastroenteritis and so it takes some time. In fact, there is a recent internet survey that showed that in about one-third of the patients it took longer than 3 years to even get this diagnosis established. And even when that child presents to their pediatrician or general practitioner who has then the thought process to refer to the specialist, even a specialist who makes the diagnosis, we know that eosinophils aren't there just because of food allergies. Eosinophils are attracted to parts of the body including the GI tract because of infection sometimes, viruses, parasites, other..reflux acid can target eosinophils so we also do our due diligence and make sure that all those other causes are systematically, deliberately ruled out before we will officially call a child as having an EGID. So it's frustrating for me in the sense that this child has taken years to come to this diagnosis. We have made sure that we've done our due diligence, ruled out all the other causes and we establish that this child has a food allergy, eosinophil GI disorders and then to have the treatment that we know works in place and then to not be able to implement that treatment because of a cost issue or the insurance not covering the medication or the treatment.

So this is just what we see when we scope children. So again the diagnosis depends on having a pediatric gastroenterologist, a child going under anesthesia to have an endoscopy done and then, not only an endoscopy, but biopsies taken. It's a long process and, you know, it got risks and benefits with that. For instance, there is actually a child in this room whose pictures these are. These are...these are big crater ulcers found in his stomach and this, basically, this yellow stuff is pus and if you look at that pus under a microscope, it is eosinophils. So eosinophils are just so heaped up there that you are finding pus-filled craters, these ulcers being formed by this food allergy. This is the same thing, pus, basically white pockets of pus seen on the lining of a food pipe or esophagus of another child, I think, who is here or may be here soon with this condition. So this is the esophagus, the normal lining should just be that pale pinkish yellow color. Here we've got a pus pockets covering it. And this is what it looks like if you see it in the stomach. This is what Jacob's case is. So these are just nodules or polyps. So if you take a section of that and look under the microscope, you are going to see tons of eosinophils.

So the treatment is, basically, to remove the offending trigger. So when we know it's not a parasite, when we know it's not acid reflux, when we've eliminated all the other causes that is causing these eosinophils to get infiltrated into the lining of the GI tract, then we remove the offending trigger. I wish it were that simple because many times our standard skin prick test, blood test that we have to try to find out allergies don't work for this because this goes through a different pathway in the body that causes the inflammation. So we may send the child to an allergist but 99% of the time we know that child is going to come back and we still don't know what they are allergic to. So we have two options; either we remove everything that we think could be possibly allergic which are the eight common food triggers, the food most children live off of, which are wheat, soy, milk, egg, nuts and fish and so either you rule out all of that. And then in a child that is already not growing or having belly pain or doesn't want to eat, you can't

let them dwindle away while you remove eight more foods. So you try to protect their nutrition that is gonna be something safe for them which is these kind of products out there. There are juices and there's milk-like substances that the children will at least want to eat or drink. At the same time, it's not harmful to them. So these are completely hypoallergenic products that don't have any allergens in them and they will replete not only a child's nutrition but protect them from any further inflammation. Sometimes we are lucky enough to only need these kind of formulas for a few months while we get that child's nutrition back up to proper standards and then we are using the process to try to figure out what that child might actually be allergic to so we try, you know, to reintroduce foods. But, for a few months at least, that child has to have these formulas to fall back on while we are trying to figure out what else we can feed that child.

Then, I know myself that the majority of the children that I diagnose with this, because this isn't covered or they can't afford it, I resort to using steroids because that also works for this condition but then I am prescribing a treatment that works and has side-effects as opposed to using a natural, side-effect free treatment because I just can't get the natural way covered by the insurance company. There is no cure for this disorder. These children have food allergies long term; although, there may be foods that they are able to tolerate later on in life. A lot of childhood allergens are out grown so it is not that they exclusively need these formulas indefinitely or lifelong. It's just that there is a crucial part of their growth when they need this to protect them.

And then that goes back to these formulas which I think I have gone over.

So they are classified as medical foods by the federal Drug Administration. They can be either drank and that is why they.. I mean, the companies are doing a pretty good job of making them better tasting so there is a subset of children who drink them and then there's a subset who need them administered through a tube and the frustration is that sometimes you get the coverage you need when the child has a tube and you won't get the coverage almost...I have never heard of a child getting covered when they are willing to drink it, which then puts us in a perplexing situation – Do we put a tube in this child? I have never done it...a surgical tube in a child just to get formula covered so that this child's nutrition is ok, or do you use medications, like steroids and things like that. So it is wrong then, I think, sometimes we think that feeding tubes is a good alternative. I mean, that is not a choice I want to be up against just to get formula covered.

I think that is the end of my presentation. If you have any questions, feel free to ask. I'll turn it over to Jeff now. Go ahead.

**ALISON MCCALLISTER:** I have a question. Jack has been on steroids since he was two and those ulcers were actually even on only 11 ingredients not like (inaudible) and even with the few food and steroids he still had that..

**DR. UMA PISHARODY:** And that's...

**ALISON MCCALLISTER:** it's really the elemental formula at the time was the only option.

**DR. UMA PISHARODY:** That's true. Steriods only work in a subset but we know that elemental diets work on virtually everybody

**SHERRY THOMAS:** I have a question

**TARA WOLFF:** I have a question for..oh, sorry.

**SHERRY THOMAS:** Go ahead

**TARA WOLFF:** Oh, Sorry. I have two so I'll just ask one. So, um, one of the things that I found confusing, and maybe you can help me understand, is you see those jars up there of formula. Umm, do they require prescriptions? Or cause, you call them medical foods and it sounds like you're the one who makes a decision about..

**DR. UMA PISHARODY:** Yes

**TARA WOLFF:** So do they require prescriptions? Or

**JEFF SCHWARTZ:** Actually, I can answer that as well, I'm going to get into those details...

**TARA WOLFF:** Oh ok, so maybe I don't need

**JEFF SCHWARTZ:** I'll let her answer from the physician's standpoint

**TARA WOLFF:** OK

**DR. UMA PISHARODY:** Yeah. Any other questions?

**JEFF SCHWARTZ:** But, I can, I'll answer

**DR. UMA PISHARODY:** He's going to address that.

**TARA WOLFF:** Ok

**JEFF SCHWARTZ:** I'll answer from a patient's standpoint. Being a medical food, it's actually classified that way because it has to be administered under a physician's care.

**TARA WOLFF:** Ok but you could get it without a prescription. You just need a physician to be overseeing

**JEFF SCHWARTZ:** Right

**TARA WOLFF:** it and telling you what really you should have for proper child.

**JEFF SCHWARTZ:** So a little further on that one... It's actually...so being a medical food. Medical foods are classified as orphan drugs and they classified as orphan drugs because of the fact that the FDA has recognized that rare diseases like EGIDs basically don't have suitable profit motivation so they have classified these set of drugs as being orphaned so that they can help encourage pharmaceutical companies to support these treatments even though there is just not enough people. And they are afforded a set of special circumstances including you'll hear over the counter or you'll hear non- prescription. That's really just the FDA blanket across all medical foods that are orphaned drugs.

**TARA WOLFF:** Ok, thank you.

**JENNIFER SANTIAGO:** I have a question.

**SHERRY THOMAS:** Go ahead

**JENNIFER SANTIAGO:** I don't know if this is going to make sense..do the cells that you showed us, the white cells that look red, do most everybody have those cells and only when you have food allergies do they react to those food allergies?

**DR. UMA PISHARODY:** We all have them most definitely in our peripheral circulating blood system. We have them in our GI tract too, minus the esophagus. So we have absolutely none in our esophagus, low numbers in our stomach and in our small intestine and then slightly larger numbers in the right side of our colon and then virtually none on our left side. Depends on which areas and that's how we make the diagnosis. If we are looking at the left colon and there's way more eosinophils than the normal right colon has, then we can say something is going on here. But if you see that same number on the left, right colon you may not think anything of it so it really depends on the number and the place to make the diagnosis.

**JENNIFER SANTIAGO:** But everybody has those cells and it's just how we.. how our body processes those...

**DR. UMA PISHARODY:** Yes, how they're localized and what the numbers are.

**JENNIFER SANTIAGO:** Great. Thank you.

**SHERRY THOMAS:** I had a question for you, doctor, about, um, because one of the questions I had reading through everything was and you answered one of them whether you see feeding tubes being administered because people can't get insurance and they can't afford the oral formula and you mentioned that you resort to using steroids sometimes because they can't afford the formula. Do you know, do you have any idea how many times you've done that based on your patient base?

**DR. UMA PISHARODY:** I'd say 90% of the time. I haven't had one patient get this covered for me and the parents will try for a while and then they can't afford it so I put all those children

on steroids. I have had one child whose parents could afford it and we went that route just because that was the option they chose.

**TARA WOLFF:** So you say you see several dozen patients and it's very, very common then for those families not to be able to afford it and not to have insurance. It's the norm.

**DR. UMA PISHARODY:** I've never heard about a patient that got it covered.

**ALISON MCCALLISTER:** I know that. (inaudible) our doctor (inaudible) at Children's only gave us the option of a feeding tube and he says that he's never seen anybody be allowed to get it orally. So even thought (inaudible) yank out a NG tube or have problems with a stomach tube, it was the only option he saw. He didn't even see oral as being an option and didn't want a feeding tube so they tried a lot of things, not just steroids, but a lot. (inaudible)

**SHERRY THOMAS:** Can you give us your name? We usually make you come up here but it's a small room. I just want to make sure in our notes that we

**ALISON MCCALLISTER:** Alison McCallister. I'm Jack McCallister's mom.

**JACK MCCALLISTER:** Hi!

**SHERRY THOMAS:** Thank you

**TARA WOLFF:** Thanks for that clarification

**JEFF SCHWARTZ:** Excellent questions. Feel free to ask me questions as I go. I'm happy to be so driven. Jacob's up here. He's my bearer of courage today. And so, Dr. Pisharody did mention that it's often not the case that people have to be on elemental formula for their entire life. A recent survey, by APFED, which is the American Partnership for Eosinophilic Disorders, did a survey distributed across the United States and some self-selected people basically responded who are dealing with EGIDS. And the survey found that 64% of people only used elemental formula for less than 2 years, because, of course, the goal of anyone that's on these elemental formulas is to food trial enough food to get a nutritious full balanced diet.

So we're going move on into some of the history in our state.

So to give you a history of where we are because this is a relatively newly diagnosed disorder but it's been around for quite a while.

In 1972, that's when medical foods became classified as orphan drugs as we were just talking about. Again, the classification is just recognition that for these rare disorders there is just no profit motivation for pharmaceuticals to basically continue to support and compete in this space, so there are certain things that they are afforded to make that happen. In 1977, is the first documented case of Eosinophilic Gastritis, which happened to have been an adult patient. Then fast forward all the way to 1995 was the first time that it was wrote about that there was a

connection between food allergies and EGIDS. All the way up to October, 2010, we finally got insurance codes. So from one sense this is a brand new disorder and the question is at what point do we help update the health care system to a new disorder? At the same time, the disorder has been around for a long time. We are just now at a point where we can successfully diagnose it more frequently.

So one of the most important things that I think, I know, are part of the criteria of the debate to discuss is what's the costs. There are really two very important pieces of cost that I want to speak about. The first one is regardless if you take the formula orally or enterally either through a G tube through your stomach or an NG tube through your nose, it is the exact same formula. There is no difference. You can either mix and drink it or mix and put it through a tube. So the cost of taking this formula either orally or enterally starts with the exact same cost. And for most families that's out of reach. \$1500 additionally a month is basically another mortgage payment and most middle-class families can't afford that. And then if you were on the path of having a G tube, which is surgically implanted, there is a number of other expenses including installation, maintenance, the actual tube supplies, rentals, and then complications from just having a tube, infections around the site, etc. In general, having a feeding tube is about 2 to 4 times more expensive than being orally fed and the dichotomy that we live in our current state is that often time insurance providers will actually pay for the tube even though it is a more expensive treatment.

Another really big question you are going to ask is how many people is this so let's talk a little bit about incident rates. Based on recent research the national average is about 1 in 2,000 people. At the same time, in our state, for whatever reason, we are slightly lower. We are about 1 in 5000 people. So to help put that in perspective, let's consider Safeco field. Let's assume that we have an even distribution of people from across our state and that they are suddenly being Mariners fans. So with that there would be only about 10 people in the stadium that would be diagnosed with an EGID. So this an extremely rare disorder. Further, well, how many people would actually need elemental food to be their treatment option? We saw that there are many treatment options and there is no one strong answer that says exactly how many people would do it but it is often cited as being 1 in 30,000 to 1 in 75,000 people who would actually benefit from this sort of insurance coverage. To put that in perspective, let's get that same even distributions on Washingtonians in Husky Stadium. There would only be about 1 or 2 people in the entire stadium that would require this kind of insurance coverage. It's very rare.

So where are we at in our current state? Our state actually has a fairly long history of both supporting medical foods and the struggle to get EGID treatment covered in our state. Starting in 1988, was when our legislature enacted a bill that made the treatment of PKU via the same medical foods a law. So our state has been supporting and funding medical foods from insurance providers since 1988 so there is nothing new from that standpoint. From 2007-2013 there have been three individual attempts to try to get expanded medical food coverage. One way to think about it is that in 1988 medical foods are covered by insurers only specifically for the treatment of PKU and really it's only since 2007 we have been trying to push that EGIDs should be part of diagnosis list so in essence it would be PKU and EGIDs.

My journey started in this whole thing around 2012 where I were an essential benefits stakeholder and then most recently in 2013 where Senator Frockt and Representative Habib successfully introduced legislative which lead us to here.

Let's make those numbers a little bit more concrete. How many people is it? In the state of Washington, we have about 6.8 million residents. Statistically we should have about 1300 patients with EGIDs. That puts us about at maybe 100-200 people that are acutely ill and would benefit from this increased coverage. I personally only know 40 families, some of which have come today and some of which are under the care of Dr. Pisharody. So now, consider the insurance coverage across the state of Washington, specifically for the treatment of EGIDS. Now this is going to be confusing and not consistent. WIC does not provide coverage for these medical formulas. Medicaid does provide coverage up through the age of 12. WSHIP program does provide coverage. Essential Health benefits as I mentioned does not provide coverage. Public Employees Health Benefit Board does provide coverage. Basic Health does provide coverage and just for reference the federal employees health benefits does provide coverage. Private insurance coverage is just not consistent. Most provide enteral only coverage. So across the board, it is just very confusing and not consistent. Even reading my own policy, I was not sure. When we were denied for coverage, I didn't know that we should have been covered.

The path ahead. As I mentioned earlier, the thing that we really need is insurance coverage for the treatment and diagnosis for Eosinophilic Gastrointestinal Disorders regardless of delivery method and regardless of age.

Now the next thing I am going to show you is there are, I guess, precedence in this states of similar legislation that have very similar findings to what EGIDs have. What I want to say upfront is that in no way am I correlating the two disorders. I'm going to be talking about diabetes and cancer. In no way am I saying that they are equivalent or in any way similar, but the findings from the legislature are similar so that's why I'm offering it.

So the first one I want to talk to you about is oral chemotherapy. IN 2010, oral chemotherapy came through a Sunrise Review just like this one. In 2011, legislation was introduced and the thing that they found was that there was an inequality on how much patients had to pay for the less expensive oral chemo which was not covered by insurance while the insurers were paying for the more expensive IV treatment, which was always covered. It's very similar with EGIDs. We are finding that intro coverage which is 2-4 times more expensive than the oral which is not covered and often times insurance policies are only paying for enteral not oral. So patients are having to pay for that out of pocket. Another analogous one is from the late 90's when our state enacted diabetes treatment. At that time, the Legislature found that there was a tremendous financial burden put upon patients even when there is an acceptable standard of care. So very similar with EGIDS. The families are having to pay up to \$1,000 or more out of pocket even though that treatment has been found 98% effective.

The great thing is that we don't have to do this alone. Looking across the nation, they are actually 14 states with coverage I found out last night and will mention in a second. And they have had coverage over a decade in some places. I wanted to highlight just a couple. Arizona

actually enacted the bill without doing any fiscal analyses. They just looked at the small incidence rate and the fact that it is classified as a rare disorder by NORD and they just passed the legislation. Minnesota, once the legislation was introduced, the private insurers just agreed to cover. There was no fight. In New York, even just as recent as last month, passed a bill that expanded coverage and so I know there is a lot of trepidation in the face of Affordable Care Act and what that could mean, other states are still making movements regardless. There is actually currently 13 states seeking increased coverage. And the reason that I say that I have my numbers wrong is that very similar to Minnesota, South Dakota actually had the exact same discovery. They went to go find insurance coverage and they found that the insurance carriers were willing to just cover it. So there are now two states in our nation that followed the path of they understand that there is a need, it is a very small population, and they have just gone and moved ahead.

Now, for me there is actually a great number for everyone that is dealing with an EGID, a great number of organizations across the nation and state that help with this. So I mentioned AFED earlier. AFED is an amazing organization. It is one of the ways that I stay connected with the volunteers across the entire nation. Then we have many members here; many compared to the number of people in the room, who are part of EMPOWER which is a local support group for families.

Final thoughts: I wanted to tell a little bit more about why I am here. I mentioned that Jacob was diagnosed with Eosinophilic Gastritis. Nice, healthy, strapping young lad here. I wanted to tell you our story. Jacob was born normal, healthy young man and at 3 months, he started to excessively spit up. We went to our pediatrician and were put on GERD medicine. Our pediatrician basically said that some babies spit up more than others. At six months, he was diagnosed with failure to thrive. His growth chart was going the wrong direction. Our story is blessed in many ways. One of which is we then spent the next month and I basically took a month off of work and we just went through every single diagnostic tool that you can imagine at the big hospitals here in Seattle. And we are very fortunate to finally get a GI specialist who did an endoscopy and who took the right biopsy. We got our diagnosis at six months which is amazingly quick given that some of my peers and friends in the community. For the next three years, he basically drank Elecare and given that it is not palatable. It is very disgusting. It is basically pre-digested proteins. We food trialed food because the goal was to get enough food so he would have a normal, nutritious diet without Elecare. And in those three years he added 13 foods and that was with a three week food trial. Bad food trials could take up to 3 weeks to stabilize during which Jacob was on Elecare as his sole source of nutrition. During that three years, my insurance provider, Premera, dropped our coverage for Elecare. The decided reason was that he didn't have a tube. Now our story happens to be blessed in many ways. We were fortunate that we had savings so that we could pay for the formula out of pocket for the time that he needed it. And then early in 2010, we had a new allergist and she recommended that we retry wheat, eggs, and milk. And they were all successful. Once the GI said I don't know what this means. And she told us that he's better. We were told that there is no cure what does that mean and she said it was a miracle. I can't explain why Jacob can eat whatever he wants now and it is actually the reason why I am here. Two years ago, my wife and I said you know what we are going to make a law. We are going to change the laws in Washington so that no one has to



balance financial stability with the health of their children and I have to pay this back. So I hope to never benefit from the coverage that I am seeking here but I think it is the right thing to do for our state.

I offer a couple hopes and pictures from our community. There are very few people that have the same story that we do. In fact, we may have a unique story in this community. But many people have the exact same story around financial hardship and the struggle with insurance providers so Connor and Jack are here today although I think they may have been noisy enough and, as I mentioned EMPOWERS is the social group we used for support. Summing it all up, we have a situation where:

- the treatment is highly effective
- the cost of treatment is out of reach for most middle class families.
- Insurance coverage in Washington is confusing or nonexistent
- There are just so few people who are impacted

So the thing they really need insurance coverage and treatment diagnosis of Eosinophilic Gastrointestinal Disorder regardless of delivery method and regardless of age.

Question?

**SHERRY THOMAS:** Do you guys have questions?

**JEFF SCHWARTZ:** That's it. That's my last slide

**SHERRY THOMAS:** I have a couple of questions...

**JEFF SCHWARTZ:** Please, fire away.

**SHERRY THOMAS:** Jacob was unique you said in that he outgrew or somehow does not have any of these allergies any more. But you also said earlier, I just want to make sure I have this clear, that a large majority of the kids only are on the elemental formula for a short time and I think that's because you are food trialing while that's going on and they are finding enough food.

**JEFF SCHWARTZ:** Good clarification. Thank you. So our goal...we did have 13 foods and let's see if I can still rattle them off. They were chicken, white rice, green beans, apples, black beans, sugar was on the list...

**CATHERINE SCHWARTZ:** And we had like tapioca starch. We had a trial for that. We were just trying to find ways to make foods for him. We eventually got almonds but we couldn't even buy rice milk or almond. I had to make it from scratch at home because the over the counter had too many other ingredients. So really the ingredients we're listing are the only things he could have.

**JEFF SCHWARTZ:** So our goal was to build up enough nutrition. It might be very boring. We had chicken for breakfast for three years. And it just might be something...if we could get enough food so that he could eat, that's what we wanted. We did not want to be...we were getting to the point with Jacob where he was still drinking out of a baby bottle at three and we knew that wouldn't last. He drank out of it because it shot it to the back of his throat and he didn't have to taste it. Many, many kids unfortunately just can't drink that. Thank you for clarifying.

**SHERRY THOMAS:** And then another, I guess, clarification. I talked to our WIC program about coverage and they indicated it is covered under the WIC program. I don't think they have a large number of the actual formula to so I wasn't sure if that's why you were saying it wasn't covered or if you weren't sure.

**JEFF SCHWARTZ:** I didn't know because insurance coverage is very confusing

**SHERRY THOMAS:** Ok well I'll do a little more

**JEFF SCHWARTZ:** based on my understanding it was not but maybe it is

**SHERRY THOMAS:** No, and when I talked to the Health Care Authority there was a little confusion on some of those programs on whether it was covered or not and you know looking at the language.

**JEFF SCHWARTZ:** It's very hard.

**SHERRY THOMAS:** Yeah, you think it's covered and then when you really look at it you're not really sure if it's covered so...

**JEFF SCHWARTZ:** 100% agreed. 100% agreed. And that's definitely... I can show you the language from my plan. I went through all of the appeals processes. The challenge of kids. So I can.

**SHERRY THOMAS:** Ok, I was just wondering

**JEFF SCHWARTZ:** Unless it actually says and there are very few plans. In fact, there are 14 states that have it say explicitly. You just don't really know.

**SHERRY THOMAS:** Any more questions?

**JENNIFER SANTIAGO:** I'm not sure if this is for you or for you.

**JEFF SCHWARTZ:** Fire away

**JENNIFER SANTIAGO:** In some of our research, we discovered that there are many different types of formulas and so I'm not sure I have a right question to ask but are there differences in formulas?

**DR. UMA PISHARODY:** And there's these words like semi-elemental, hypoallergenic that many formulas will be labeled but they are not the treatment for this. For this, you really need amino acids. If you take a protein down into its building blocks - amino acids, that's what we mean when it's an elemental formula. As far as I know, there are only three: Elecare, Neocate and then there is a new one called Nutramegin AA that (inaudible) use but these things are all peptimem and there is semi-elemental and hypoallergenicly labeled but they are not amino acid based and they don't count. They are treatments for other things but they are not treatments for this.

**JENNIFER SANTIAGO:** But they are not treatments for this?

**CATHERINE SCWARTZ:** We tried some of those first in the interim, because we were hoping that maybe he could...that would work but no, there was still excessive vomiting. He couldn't keep it down. We had to go purely elemental.

**JEFF SCHWARTZ:** Perhaps if you saw... Pregestimil, was that the one we had?

**CATHERINE SCWARTZ:** We tried Pregestimil. We tried Alumentum. We tried...

**JEFF SCHWARTZ:** That's when we spent a week in the hospital. He was actually on that. We found that that didn't work.

**DR. UMA PISHARODY:** When you take the protein and you kind of break it down but not really, they're still somewhat broken down, they are considered semi-hypoallergenic or something like that.

**JENNIFER SANTIAGO:** Does the FDA consider those formulas medical foods but they are just not the appropriate medical foods for this disorder?

**DR. UMA PISHARODY:** I don't really know the answer to that.

**JEFF SCHWARTZ:** I'm not sure. I don't know.

**JENNIFER SANTIAGO:** Ok.

**JEFF SCHWARTZ:** That's a good question.

**JENNIFER SANTIAGO:** And then...

**JEFF SCHWARTZ:** I'd be happy to do follow-up on that

**JENNIFER SANTIAGO:** Follow-up to that question is where would you obtain it? You don't physically write a prescription for this type of...Oh, you do.

**DR. UMA PISHARODY:** Yes.

**JENNIFER SANTIAGO:** Do you utilize that prescription to obtain it from a pharmacy?

**CATHERINE SCHWARTZ:** It depends.

**JEFF SCHWARTZ:** In most cases, you have to go through a DME company, durable medical equipment, is where we often...

**DR. UMA PISHARODY:** So for like the kids who have WIC. WIC doesn't have it in their office so WIC will give them a letter that says we don't carry it. So they take that letter and my prescription to their pharmacy and the pharmacy will order it for them.

**JENNIFER SANTIAGO:** But it's through a pharmacy. You don't go directly to this company and purchase it. I mean, it is actually being evaluated by a pharmacist and being distributed by a pharmacist.

**ALLISON MCCALLISTER:** You can do both. Through this company, you have to give them your doctor's information, phone number and contact information for your doctor and the company will send (inaudible). And they have a whole process in place. (inaudible) But if you are really, really struggling, they have connections they can make with certain medical companies for costs and that helps a lot. (inaudible) They try to make it helpful. They want to sell the product. They try to do everything they can to make it easy.

**JENNIFER SANTIAGO** Based on the small numbers of this, I assume that not every pharmacy is able to assist you.

(Several people talking at once)

**CATHERINE SWARTZ:** Yeah, you can't just walk in. They don't just carry it.

**TARA WOLFF:** That probably helps explain that price differential we saw. You are saying only three products are appropriate and all those products are they kind of in the same price configuration?

**DR. UMA PISHARODY:** And so the three products that I mentioned are specifically for infants. There are some elemental formulas for older people (inaudible). We don't really use them but the three that are most being prescribed for infant formulas and then they have older child formulations of them. So I think that they are all about the same price. They are about three or four times the cost of a normal formula. If you were to take Similac and compare it, it's cost is about three to four times.

**JEFF SCHWARTZ:** To kind of put that down in concrete. So Jacob was drinking at one year a can every two days and it was basically \$40 a can. He was eating \$20 worth of food every day. I don't even eat that much food every day.

**ALLISON MCCALLISTER:** And he was a one year old (inaudible).

**JEFF SCHWARTZ:** Right

**JEFF SCHWARTZ:** So back to through a physician's care. As you will notice, there's mixing ingredients but it's not like Gatorade. We are basically taking a caloric intake that was higher because we needed to gain more weight and that's all under a physician's care. So even if I bought it off the street, I wouldn't know how to mix it.

**SHERRY THOMAS:** Anymore questions for Mr. Schwartz? No?

**JEFF SCHWARTZ:** Thank you

**TARA WOLFF:** Thank you

**SHERRY THOMAS:** Some of you are probably signed up for testimony, right?

<Background conversation inaudible>

**SHERRY THOMAS:** It's time to take public testimony and I was going to say we'll call you up in the order you signed in although, looking at this, I'm not seeing any checkmarks for actually testifying so I think...What's your name?

**ANGIE VOS:** My name is Angie Vos

**SHERRY THOMAS:** Ok. Does anybody else want to testify after Ms. Vos?

**JEFF SCHWARTZ:** Yes

**ANGIE VOS:** I guess there are two more that are here. They are out with their children.

**SHERRY THOMAS:** Why don't you come up and I'll go....will you guys go and check with those folks and have them come in?

**JEFF SCHWARTZ:** As Angie's coming up, I actually have three people providing written testimony so I was curious to see how you want to handle that. We can read them or submit them. Your choice.

**SHERRY THOMAS:** We can just take them if you'd like unless they wanted you to read them. If they would prefer that you read them.

**JEFF SCHWARTZ:** Ok, good, I'll read them.

**SHERRY THOMAS:** We have time.

**JEFF SCHWARTZ:** I shall read them.

**SHERRY THOMAS:** OK

**ANGIE VOS:** Good morning and thank you for allowing me to speak today. My name is Angie Vos. I'm here to help put a face to this important issue and to urge you to support this legislation. Unfortunately, my son, Hayden is with his father for the remainder of July so all I can show is this picture of him and tell our story.

Not long ago, I was successful professional with two Bachelor's degrees on my way to earning a decent living as a landscape architect. I had raised two sons while going to college and I didn't think more children would interfere with my career plans. Hayden was born October 2007, and from the beginning, it was clear that something wasn't right. He either spit up or projectile vomited 10 to 20 times a day. He would always seem to be in pain. I was told that he just has gas and some babies just spit up a lot. Ours was essentially a (inaudible) problem. Our focus was always on his life-threatening allergy to milk. After a number of anaphylactic reactions to milk based formula, he refused all formulas by four months. His doctors told me that he couldn't possibly get enough milk protein through my breast milk to be concerned and I believed them. While his growth was slow, he was growing. Eventually his doctor relented that he might have reflux or GERD but that it would probably resolve on its own by six to 12 months when the sphincter at the top of his stomach closed fully. I introduced foods early and switched from breastfeeding to soy milk at around 12 months. His symptoms disappeared almost instantly. At two, however, he started having diarrhea. I took him to his pediatrician, allergist and two pediatric gastroenterologists. After 6 months of chronic diarrhea, he was finally diagnosed with Eosinophilic Esophagitis and dozens more allergies. The trauma of the diagnosis lasted about a year. I had to replace the boxed and canned and prepackaged foods that I relied on as a single working mom. I learned about vegan top eight free cooking, about vegan top eight free nutrition, hypoallergenic shopping and I read everything I could get my hands on about EGIDs. It was during that time that Catriona Colerick and I founded EMPOWER late in 2010. Our hope was to connect with other families dealing with EGIDs and organize our resources to help each other. After networking with hundreds of others dealing with these same conditions around the world, I had come to realize that we were lucky to get our diagnosis in just two and a half years. It was also during this time that I could no longer make ends meet. Medical bills, one on one childcare, the ever-changing diet, time off work, doctor's appointments, legal battles with their father and stress had reduced me to part-time employment and losing my own medical coverage and increasing our reliance on public assistance to meet my children's basic needs. I can't imagine earning enough to cover it all but some families try to. I was, initially, told that his insurance, Medicaid, would cover formula if we needed it regardless of method of delivery. We tried samples of amino acid based formula early with Hayden as we stripped every potential trigger from his diet. He could detect and refused even the smallest amount of formula in every

concoction we could whip up. There was no getting him to drink it. Luckily, he achieved remission through dietary elimination and he only lost a few pounds in the process. We avoided a tube that time. He relapsed, however, at four and a half and for the past year, I have struggled to find out what changed. Talk of a feeding tube has been brought up several times as we remove and add (inaudible). We constantly weave back and forth between adequate and inadequate nutrition. If formula were deemed medically necessary again, I can't imagine ever getting him to drink it for supplemental sole source nutrition but somehow I could. We are lucky, we have Medicaid. Those families who manage to stay together and maintain private insurance avoiding this dependence on Medicaid should be congratulated, not punished. Likewise, those families who succeed in drinking those unpalatable medical foods should be congratulated, not punished. With your help, the expensive formula, an expense that can easily rival that of a mortgage, won't break those families too. I can see how the State may even see a cost saving and have fewer families like ours go on public assistance and Medicaid. I appreciate your time and consideration. Thank you.

**SHERRY THOMAS:** Any questions? Thank you. Are you wanting to testify?

**CATRIONA COLERICK:** Yes.

**SHERRY THOMAS:** Ok, and you are?

**CATRIONA COLERICK:** Catriona Colerick.

**SHERRY THOMAS:** Oh, are you not on here yet?

**CATRIONA COLERICK:** I signed up.

**SHERRY THOMAS:** There may be another list up there. Oh, ok. Come on up.

**CATRIONA COLERICK:** Thank you.

**SHERRY THOMAS:** I just want to make sure we have your information so that we document it.

**CATRIONA COLERICK:** Hello. Thank you for having me. My name is Catriona Colerick and I'm here about my son, Connor. In Dec 2010, my son, Connor, was diagnosed with Eosinophilic esophagitis, one of the conditions we are referring to when talk about Eosinophilic gastrointestinal disorders or EGIDs. Since Connor's diagnosis, my life has revolved around this rare disease. In 2011, after months of networking and trying to connect with the other families, Angie Vos and I co-founded EMPOWER, Eos Moms and Pops Organizing Washington Eosinophilic Resources. This is one of the only support groups for families in Washington State living with EGIDs trying to connect with one another. In our first two years, this group has grown from just my and Angie's two families to over 38 throughout Washington State. In my community, there are two types of lucky EGIDs patients; ones who can eat food, which my son, Connor, cannot and the one whose insurance covers elemental formula. I did not feel lucky the

first time Connor's Medicaid denied to cover his elemental formula. We are with Molina, who is one of the managed healthcare plans that Medicaid will send you to. My memories of Connor's first months were that of a still and screaming infant who could barely gasped for breath between fits of projectile vomiting. Everything we fed him made him sicker. Medically he was failing to thrive. Cognitively he was not progressing. Allergic to breast milk and every formula on supermarket shelves I honestly wondered if my son would make it to his first birthday. So when Connor was four months old, I purchased Connor's first case of elemental formula for \$100 off of Craig's list. I met a woman in a 7-11 parking lot and bought medical food for my child from a total stranger as a last ditch effort to help my baby. It was scary but it worked. And in that first week, we could see that Connor was getting better. I then went to my doctor who told me to go to WIC and there at WIC I was told that they would not cover elemental formula and I got a letter from them denying it because they do not cover it to give to our insurance company. At \$134 a case, which is only four cans, I had no way to afford elemental formula on my own. Our doctor submitted our request to insurance and a week later, I called in to find out that we were denied. So I called back and said he needs this formula. He is sick and it was then that I was told that if he had a feeding tube that there was coverage. But that I needed to wait and I could fight our denial to have it covered by mouth. And so I kept calling my insurance company sometimes daily and our decision was appealed when I was finally told that we could go through a, I wish I knew the name..

**JEFF SCHWARTZ:** A DME?

**CATRIONA COLERICK:** a DME option for nutritional supplements. So we are one of the lucky ones because my son can go and thrive and we didn't have to file bankruptcy to feed him but not all Washington families are so lucky. There are people in my community right now who are shouldering this cost alone. Studies will show that 96% of patients on an elemental diet achieve remission. Connor's elemental diet, his sole source of nutrition at this time, comes to \$825, which is over 80% of my monthly income as a single mother of two. Yet it is a mere fraction of the cost of inserting and maintaining a feeding tube. Every person diagnosed with Eosinophilic gastrointestinal disorder deserves to eat and not just the lucky ones. Thank you very much for your time and I am open to any questions. Thank you.

**SHERRY THOMAS:** Thanks.

**TARA WOLFF:** Thank you.

**SHERRY THOMAS:** I think that should be everybody. And then you are going to read. How many do you have?

**JEFF SCHWARTZ:** I can read some of them and perhaps give an option to have... so the three families couldn't come today. One actually, Jennifer Harris, lives out of state but she has Washington insurance. She provided written testimony. We have a family in our state that actually has an out of state insurance. And she told her story about how having her insurance plan in Illinois basically has made this process so much easier. She just has coverage. So even though she is in my community, she doesn't have to deal with insurance problems. And



then one other woman in our community she has it as an adult. So that is the three sets of testimony that I have.

**SHERRY THOMAS:** Go ahead and read them. I think we have time and we can go ahead and get it on record.

**JEFF SCHWARTZ:** Ok, great. I shall. So then I will just for supposed I will go ahead and read Jennifer's. It is written in first person. I swear my name is not Jennifer but I'll read it that way.

To Whom It May Concern,

My name is Jennifer Harris and I live in Alabama but my private insurance policy comes from Washington State. I am writing today in hopes that you will reconsider the coverage of elemental formula for ALL children with Eosinophilic disorders. At the end of 2011, my son, Michael, was diagnosed with Hyper-eosinophilia, Eosinophilic Gastroenteritis and Failure to Thrive. His symptoms include headaches, difficulty swallowing, reflux, abdominal pain, diarrhea, food aversion and failure to thrive. Because of this Michael is unable to eat anything with milk, egg, soy, wheat, potato, corn, sweet potato, rice, peanuts, tree nuts, and almonds. Now ask yourself, how would you feed your child with those restrictions? Children with Eosinophilic disorders are unable to absorb enough nutrients from food to sustain life. At the time of diagnosis (Nov 2011) Michael had just turned 14 years old and weighed only 65lbs. He began the Elecare formula in December of 2011 as his only source of nutrition and has since gained almost 30lbs and grown several inches. He will be 16 in November and now weighs 93lbs; this would not have been possible without the Elecare formula. For the first time in his life he is not in pain, he is growing, and beginning to have enough energy to play. Unfortunately, our family and many others like us do not have the means to pay for this formula. It is my understanding that if he had a feeding tube this formula would most likely be covered by private insurance. This is both frustrating and perplexing to me. If he had a feeding tube I would be sent the exact same can of formula, I would mix it the exact same way, the only difference is that he is drinking it instead of taking it through a tube. He is willing to drink the formula; he absolutely hates it, but is willing to drink it because he realizes that he needs it to live. It is absurd that Michael or any other child would have to undergo an unnecessary medical procedure just so they can get the formula they need to live. The feeding tube will cause further complications. I understand that the cost of the formula is expensive but it seems to me that it would be more cost effective for the insurance companies to cover the formula with him drinking it as opposed to an unnecessary medical procedure and all of the complications and cost that come with it. As of October 31, 2012, my son's secondary insurance, Alabama Medicaid, which had been covering the formula, became inactive and we do not have the means to pay for it.

This nearly forced us into foreclosure. I would like to point out that state Medicaid agencies will cover the cost of formula with prior authorization from a doctor, thereby acknowledging that the formula is of medical necessity. Why is this any different for private insurance? I fear that if my son no longer has the formula he will once again become emaciated and very sick. I realize that our children are just another name and number that floats by on a piece of paper which ends up in filing cabinet but to us they are our world and because of this, I am asking you to please cover this formula. My insurer's actions seem to say to me that this is not as important issue but to my son and all other families with Eosinophilic disorders this is very urgent. Parents of sick children should be able to focus solely on the care and well-being of their family. Unfortunately, that has not been the experience for the parents of children with Eosinophilic disorders. We wake up every day to plead, beg, cry, and fight to get the coverage for these medical formula our children so desperately need. Ask yourself, what would you do if they were your children?

Sincerely, Jennifer Harris

Then I'd like to read on behalf of Laura.

My name is Laura. My youngest daughter has Eosinophilic disorder in addition to mitochondrial disease, asthma, osteoporosis, and an autoimmune condition. After many years trying locally to find out what was wrong with my daughter, who is 6 years old, and had food refusal, failure to thrive, cried all the time and generally was miserable, we flew out to Cincinnati Children's Hospital. There she was diagnosed with having Eosinophilic enteropathy. Eosinophilic cells existed throughout her entire GI tract. Already on a very limited diet due to her extensive food allergies, she started Neocate Junior, a completely, 100% elemental formula. It has no intact protein and sugar is already broken down to basically all glucose. This is not the same as Ensure or other formulas that are partially hydrolyzed. Those still have intact proteins and sugars that the body can react to and still has to work to break down. At seven and a half, she was 36 pounds and quickly losing weight. She was not able to drink enough of the formula and was not able to stand the taste. We had a tube placed down her nose and into her stomach. She had that for 3 months and put on 10 pounds after having a sinus infection from the NG tube and G tube was placed. She is now 13 years old and has the G tube. She is still 100% formula only with no known safe foods, not even sugar is safe for her because it turns out that she doesn't even produce the enzymes to break down the sugars or most carbs. The Eosinophilic enteropathy diagnosis and being placed on a strictly formula only diet most likely saved her life. Food makes her that sick. We are very fortunate because in spite of high medical bills we have formula coverage under my husband's policy, Blue Shield/Blue Cross of Illinois. Because the parents and legislature in Illinois lobbied for coverage regardless of who it was consumed our policy covered it regardless if she had a feeding tube or not. We just had to fax the DME letter of necessity, the diagnosis and a copy of her allergy-testing showing that she was allergic to everything. The DME did all the work. Someone did the lobbying in Illinois that

benefitted us, which is why I want to help. My daughter is now 13 and will most likely need this formula or total parental nutrition for the rest of her life. She uses 30 to 34 cans a month. This is a medical formula. A lot of people ask why she has a feeding tube; I simply have them taste it. If a child can stand drinking that formula, they should not be punished by having an insurance company refuse to pay for it. I cannot imagine having to pay out of pocket for the formula in addition to the co-pays, deductibles, prescription, the hotel and airfare out of state doctors to diagnose the condition. Even with the insurance paying for my daughter's formula we barely make ends meet. Our order for the formula cost around \$935 a month. Through the durable medical supplies, our insurance required us to use is much higher. Even at \$935, a month the cost of formula is out of reach. The argument that formula coverage will increase the cost of policies is simply not true. It is covered in our state like Illinois. Very few children are like mine and stay on it long term. Having to have a feeding tube placed solely for the purpose of having formula coverage through your insurance is not the easiest or least expensive answer let alone the emotional trauma a child faces when having a tube placed regardless if it is short term or long term. There are risks and additional costs to having a feeding tube placed. Even a NG tube through the nose requires a hospital stay. Having a G tube surgery is invasive painful and there is always the chance of infection or perforation or misplacing the tube. There can be complications. My daughter has been hospitalized for MRSA at her tube site. It is very scary to see how rapidly your children's health can deteriorate due to an infection like that. She has had it twice. She now needs (inaudible) in this hospital for intervention, radiology to place her newer GE tube that goes past her stomach. There are her supplies that goes with her feeding tube. She has to have a feeding tube pump approximately \$2000; feeding bags \$200-\$250 a month; feeding tubes, extensions, syringes etc. and cost of the feeding tube being placed simply to lower the expense of formula does not lower cost answer. An alternative answer to keeping cost down would be to allow us to purchase the formula directly from Neocate who tries very hard to keep the cost down for medically fragile kids and their families. Prior to purchase through a durable medical supplier, they mark it up often 300%. My insurance is billed \$10,000 a month. They probably pay \$2100 for their supplies. Changing the way formula is reimbursed could simply be a bigger cost saving than refusing formula coverage completely. Even though I could not be there in person, thank you for listening to our story. I hope you are seeing other states can do this and do successfully provide formula coverage. Hopefully, It will help those in Washington to get it covered for those diagnosed with the disease.

So that was from Laura. And the last one is testimony from Jessica Yem:

Hi, my name is Jessica Yem. I am both a 36-year-old patient and a parent of a child with Eosinophilic gastrointestinal disease. After dealing with numerous and increasingly life-threatening food allergies and food intolerances since infancy, my daughter, Jayden, was finally diagnosed in 2010 with Eosinophilic Esophagitis or EOE. Her diagnoses has since expanded to Eosinophilic Gastroenteritis or EGE, as the disease affects her entire GI tract from esophagus to colon. At the time of her diagnosis, she was down to only a handful of safe foods and continuing to have new reactions. We felt like elemental

formula was our best option to get the disease into remission and to give her the nutrition she needed. We found an elemental formula, Neocate Splash, that she seemed to tolerate and the dietician advised us that we should have five juice boxes totaling 40 oz. every day. We set up an account with a medical supply company, which we were required by insurance to use and requested our first delivery. My hopes were set on getting insurance coverage as purchasing this through the medical supply company myself would have cost us over \$17.00 per juice box. So around \$85 per day. For over \$2500 per month. Insurance immediately denied the claim. Even after receiving a letter from her doctor's office stating that she had only two safe foods to eat, broccoli and lamb, they still denied for that very reason, that she had two safe foods. After a period of weeks and many phone calls on my cell, the GI office and the medical supply company explaining that my daughter couldn't survive on only two foods, the insurance company finally authorized her formula. The following months she did lose those two foods and went to 100% formula intake. In 2012 I was diagnosed with severe EOE and was put on elemental formula for a month to get my disease under control. My formula would have cost over \$5000 a month through the medical supply company. I am sure that Molina initially denied the claim stating that supplements were specifically excluded on the plan. I called and explained this was medical food and not a supplement and that it would be providing 100% of my nutrition and they weren't interested. I kept getting conflicting information. One person said that it was never covered regardless of the reason. One person said that it would be covered for medical necessity. Thankfully, after a letter from my doctor, the decision reversed and my formula was covered. The process of getting coverage for both of us was incredibly frustrating and time consuming. And had we not gotten our formula covered, I don't think I have to tell you how devastating that would have been on my family. Because of Jayden's as well as my own health issues, I have not returned to work since. We are a one income family and my partner works as a low voltage union electrician making less than median income for King County where we live. We have had to travel out of state for my daughter's care. We have incurred many medical expenses and lost wages. Formula cost alone for Jayden and I alone would have exceeded our entire income last year. Medical studies have shown that an elemental diet is one of the most effective treatments for this disease putting in remission up to 96% of patients with EOE. But the cost is prohibitive for many families and many insurance companies look at it as a supplement, like any vitamin you might buy in the store. Elemental formula is not a supplement; it is a medical food, and it is often a child's sole source of nutrition. We are fortunate in that fact that my daughter would have taken her formula orally and didn't require a tube to be surgically placed in her stomach for nutrition. Many children won't or can't partially because of the taste and partially because it is just too hard to consume that much liquid in a day. Many insurance plans will only cover elemental formula as given through a tube even the same treatment benefits can be seen by taking it orally. I implore you to consider this bill and consider mandatory formula coverage for EGID patients. Not all EGID patient will need formula as part of their treatment. Not even the majority of EGID patients will need elemental formula. But for those patients whose case is severe, elemental formula can literally be lifesaving.

(inaudible background talking)

**TARA WOLFF:** Can I ask a question of John?

**SHERRY THOMAS:** Yes

**TARA WOLFF:** I have one more question. I not sure who to direct it to. For EGID does that have to be diagnosed by a pediatrician with a gastrointestinal specialty?

Inaudible

**TARA WOLFF:** So it does need that for the diagnostic. And just one other question about our state. You talked about a family that had needed to travel in order to...so in our state, it's a pretty big state, and I know that specialists are not distributed evenly across the state, is that a further...are there barrier for families who are looking for that kind of specialist to help them figure out that type...

**DR. UMA PISHARODY:** There's three or five gastroenterologist in Tacoma. There's also six or seven at Seattle Children's (inaudible) and there are two of us at Swedish and there are three or four in Spokane.

**SARA MCCALLISTER:** Most of those guys don't really perform those. It's been my experience as a parent. It took five years for a diagnosis and his allergies started before he was two years old but we had to see a gastroenterologist before they would even scope it.

**TARA WOLFF:** So is the hesitancy about scoping is that the pain or the risk to the child?

**JEFF SCHWARTZ:** Well, anesthesia. They have to put the children all the way out.

**TARA WOLFF:** So that's a risk to the child?

**JEFF SCHWARTZ:** Oh, from my point of view as a parent, that's something we definitely...even being highly allergic we weren't on the new anesthesia. We were on the old stuff because the new one, I don't know what they are called, but it was soy based so we took the ancient one. It took Jacob hours to come out of anesthesia. It was very scary.

**TARA WOLFF:** I see. So that would be the hesitancy about...

**JEFF SCHWARTZ:** Right

**ALISON MCCALLISTER:** And that would be the...

**SHERRY THOMAS:** Can you come back up front so we can all hear?

(talking all at once)

Come up to the panel

**ANGIE VOS:** I'd like to add too that this is such a newly recognized diagnosed disorder. There are very few doctors who really appreciate or understand what's going on and as I understand just in medical exams last year in that so we are just seeing doctors who have been educated unless they have trained at a specialty clinic and there are only five or six throughout the country. The understanding and I don't have a doctor that was trained in, I don't have a doctor that was educated in but he has an interested in and that's the best I can get right now and I'm grateful for it after...this is our third gastroenterologist. We have at least...

**ALISON MCCALLISTER:** I like to sort of add to that. With my son, he not only has eosinophil problems but he also has IgE allergies are to all, his IgE allergies are to all the great foods, they have tested 80 plus foods for him. It's not just a (audible) positive, it's prick positive and reaction positive. It took years to convince them that it wasn't just (inaudible) food trials that would set him back four plus months. Every reaction meant respiratory arrest, he was on cough syrup (inaudible). He's contact allergic. In school every day no matter how much cleaning they do, he'd be covered in hives. He is allergic to all foods pretty much; all fruits except for pears, he was a contact allergic. So now we had to find the ones that were eosinophil triggers versus the ones that were the IgE triggers. In order to keep him alive, we had to feed him IgE allergies and he has to be on steroids constantly not just swallowed topical steroids but prednisone, systemics steroids. He not only had those kinds of reactions he started having joint inflammation that we first thought was juvenile rheumatoid arthritis but found out it was actually reactive arthritis to his EGIDs. So these kids don't just have their GI part of their bodies disintegrating, their joints are affected, his liver has problems, he gets neuro problems, neuropathy pain and headaches. When they do things like MRIs, they have to first prick test and patch test the contrast I think it is and the anesthesia that they use. So putting these kids under if they have more than just the one issue becomes a nightmare in and of itself. Just to get that done took long time. So they were pretty much (inaudible) before they were really ever biopsied. It got so bad. I think he lost 10 pounds in three months at five years old and he had ulcers that they couldn't even biopsy until they got them partially healed. They were so thin, they were afraid they would perforate his stomach. There are those two diagnostics (inaudible). At that point with those ulcers, he was on only 11 ingredients and some of those ingredients were IgE allergens we had to counteract with steroids. Just to give you guys some idea. It's not common. Kids like ours are really rare because these are the kids the schools don't know how to deal with. I had to work with an ombudsman just to get him school. It's not going to be a huge cost for the insurance companies to cover these really rare cases. Most people are going to do a top six or top eight food elimination diet and their kids are going to see improvement. My kid didn't even have the top eight. We can't even touch the top eight so there's that issue. You know it's like the peanut allergies you hear about (inaudible). Oh and as far as orally taking it versus a tube, he was willing to. We had a party, we set out cups, we got 100% artificial chemical flavoring agent. We put a drop in each one, you know, each cup of formula and we went around the whole family and we tried them and decided which one was our favorite. His favorite was very different from my favorite. I don't know how he tolerated it. But we let him try it and decide which one was

more palatable, which one was better to drink so he didn't have to have surgery. It was a big, big money saver to get a drop of flavoring and add it to a formula. (inaudible). (laughter)

**SHERRY THOMAS:** So I guess just next steps:

- There is an additional 14-day written comment period and so we may call up with questions you all too because it's so complicated that we may have some. Through August 5 at 5:00 you can submit additional information or if you find anymore data.
- In September we will share the initial draft report for comments. We open up a rebuttal period, so if you don't like what we say, you get a chance to write back to us and tell us why or to correct things if you see something that is just an error. We will actually either incorporate those rebuttal comments and changes in the report or not. Either way we include them in the report and we will actually address in the report why or why not we did not if we don't make changes. The report gets pretty large because we try to put everything in it.
- Probably around early October, we will send it to the Secretary of Health for him to actually approve it.
- After that approval process, it goes to the Office of Financial. So we try to get it to the Legislature around the first week of December.
- Once that happens, we will post it to our Web site once the legislature receives it.

### Hearing Participants

<b>Name</b>	<b>Representing</b>	<b>Position on Proposal</b>
Jeff Schwartz	Applicant	Pro
Uma Pisharadoy	Applicant	Pro
Sara McCallister	Self	None
Dinesh Thekke-Karumathil	Self	Pro
Donna Dorris	Office of the Insurance Comm.	None
Catherine Schwartz	Self	Pro
Jacob Schwartz	Self	Pro
Sam Schwartz	Self	Pro
Claire Colerich	Self	Pro
Connor Colerich	Self	Pro
Angie Vos	Self	Pro
Catriona Colerick	Self	Pro
Jessica Young	Self	None
Laura Griffey	Self	None
Alison McCallister	Self	None
Jack McCallister	Self	None

(ē'ō-sī-n'əfī-l)

**Eosinophilic Gastrointestinal Disorders**

**Washington State Department of Health Sunrise Review**

July 22, 2013

Jeff Schwartz, father of son with Eosinophilic Gastritis

Dr. Uma Pisharody, Pediatric Gastroenterologist Specialist



# Today

Overview of Eosinophilic Gastrointestinal Disorders

Current state in Washington State

The path ahead

Final thoughts

# What is needed?

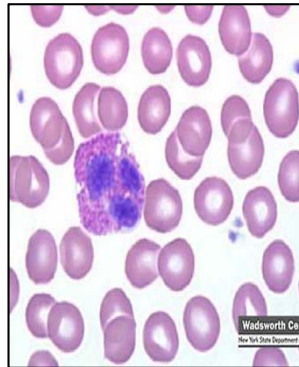
**Insurance coverage for the treatment  
and diagnosis of Eosinophilic  
Gastrointestinal Disorders, regardless  
of delivery method (enteral or oral)  
and regardless of age**

# **Overview of Eosinophilic Gastrointestinal Disorders**

# Eosinophils

Eosinophils are white blood cells whose sole purpose is to fight off harmful foreign substances

Eosinophilic Gastrointestinal Disorders (EGIDs) are a group of allergic diseases and genetic disorder where the eosinophils act as if food is a harmful foreign substance and attack the gastro-intestinal system

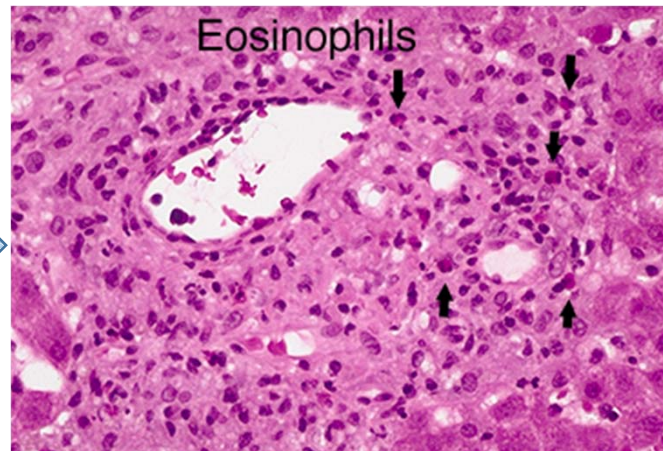
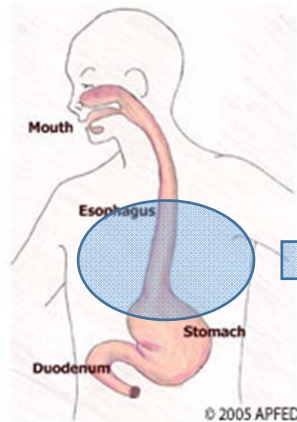


**Food is poison for those suffering with this disorder**

# Eosinophilic Gastrointestinal Disorders

- Eosinophilic Esophagitis (EoE): esophagus
- Eosinophilic Gastritis (EG): stomach
- Eosinophilic Gastroenteritis (EGE): stomach and small intestine
- Eosinophilic Colitis (EC): large intestine

Upper  
gastrointestinal  
tract



Biopsy examined  
under microscope

# Symptoms

- Vomiting, nausea
- Diarrhea
- Failure to thrive
- Severe abdominal pain
- Poor growth
- Fatigue
- Feeding issues
- Anemia
- Food impactions
- Chest pain

**“Other causes of gastrointestinal eosinophilia must have been ruled out for the diagnosis of EGIDs to be confirmed”\***

**Recent internet survey showed that 35% of patients took longer than 3 years to get a diagnosis\*\***

\*Journal of Pediatric Gastroenterology and Nutrition  
47:234–238 # 2008 by European Society for Pediatric Gastroenterology, Hepatology, and Nutrition and  
North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition

\*\* An Internet-based survey of self-reported data in 2012 collected by the American Partnership for Eosinophilic Disorders (a national non-profit patient advocacy organization) based on input across the United States

# Diagnosis

Doctors use an upper and lower endoscopy

For children, this often means general anesthesia



Jack McCallister – diagnosed with Eosinophilic Gastroenteritis



Connor Colerick - diagnosed with Eosinophilic Esophagitis



Polypoid nodules caused by Eosinophilic Gastritis

# Treatment

## Dietary treatment

1. Restrict diet based on allergy testing
2. Elimination diet (avoid top allergens)
3. Strict use of an elemental formula (98% effective)

## Ingested steroids

**There is no cure for this disorder**



Figure 1: The "Big Eight" Allergens: Tree Nuts, Peanut, Soy, Egg, Milk, Fish, Wheat and Shellfish.



# Elemental formula

- Classified as a medical food by the FDA
- Administered orally or enterally (feeding tube) under the direction of a physician
- Completely non-allergenic food
- Gastrostomy-Tubes (G-Tubes) are placed surgically and require maintenance
- Feeding tubes and supplies are often covered by insurance whereas oral is not

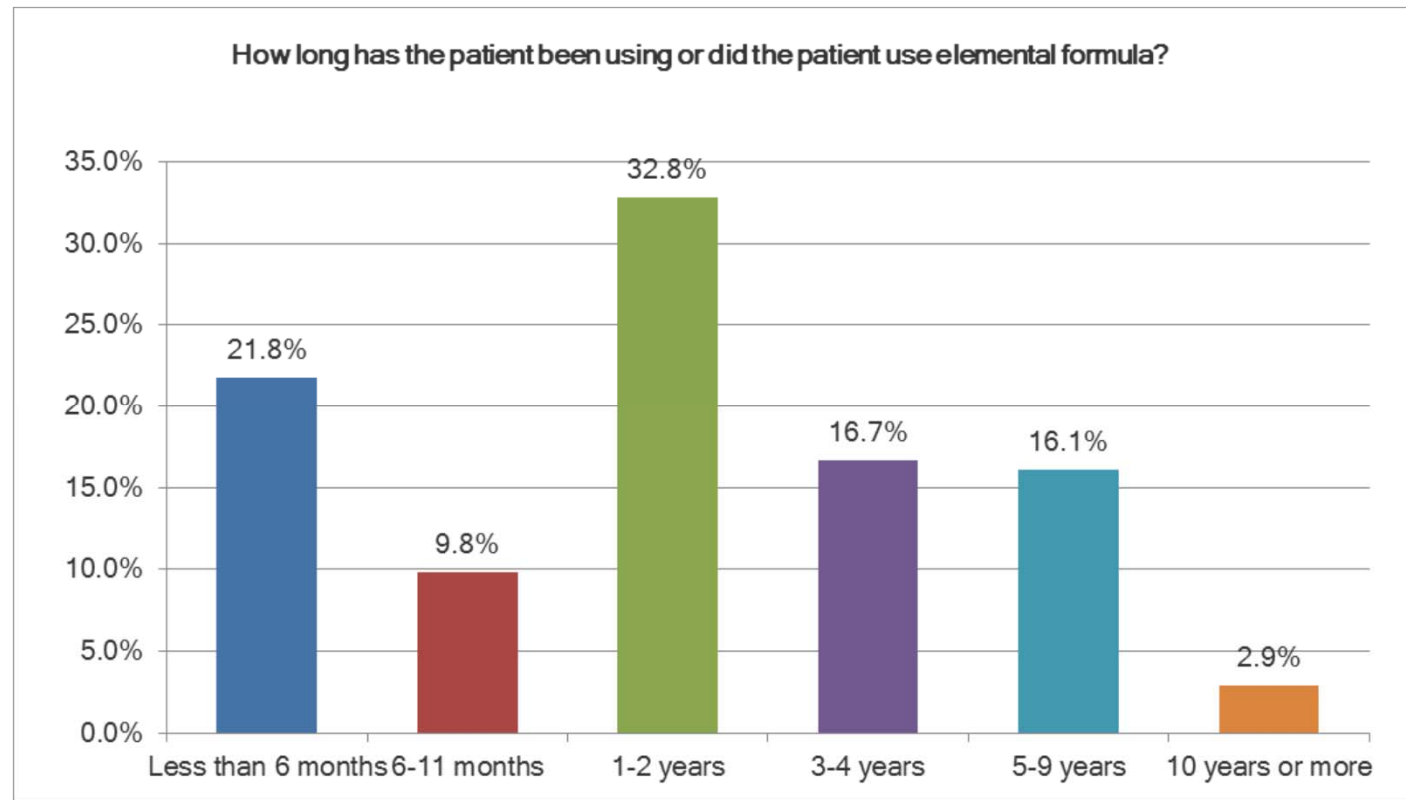


**It is wrong that feeding tubes are the affordable choice**

# Elemental Formula Usage

64% of people use elemental formula for only 2 years

Elemental formula delivers safe nutrition while food trialing



**The goal is to trial enough food to build a complete diet**

# History

1972 – Medical foods classified as ‘orphaned drugs’ by FDA

1977 – First patient diagnosed with Eosinophilic Esophagitis (adult patient)

1995 – Link established between food allergies and EGIDs

2010 – EGID insurance codes introduced

**When is the right time to cover a new disorder?**

# Elemental Formula Cost

Elecare/Neocate  
\$40-\$60 a can

Number of cans per day determined by physician based on age and daily caloric/nutritional need

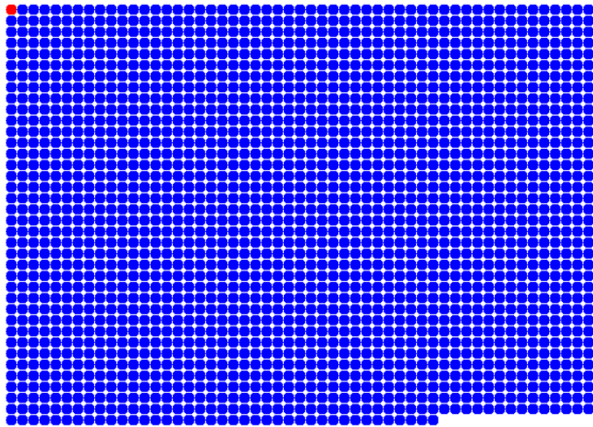
Expenses	Jacob (age 3)	Gastrostomy-Tube Feed
Medical Food	\$1,000-\$1,5000	\$1,000-\$1,5000
Tube Supplies		\$1,000
Tube Adjustment (surgical)		>\$1,000 (every 3-6 months)
Pump Rental		\$300
Initial Installation		>\$1,000
<b>Monthly</b>	<b>\$1,000-\$1,5000</b>	<b>\$3,000-\$4,0000</b>
<b>Annual</b>	<b>\$12,000-\$18,000</b>	<b>\$36,000-\$48,000</b>

**“This would raise premiums 1.6 pennies a year for the average family.”**  
**-- Ohio State Senator Krebs**

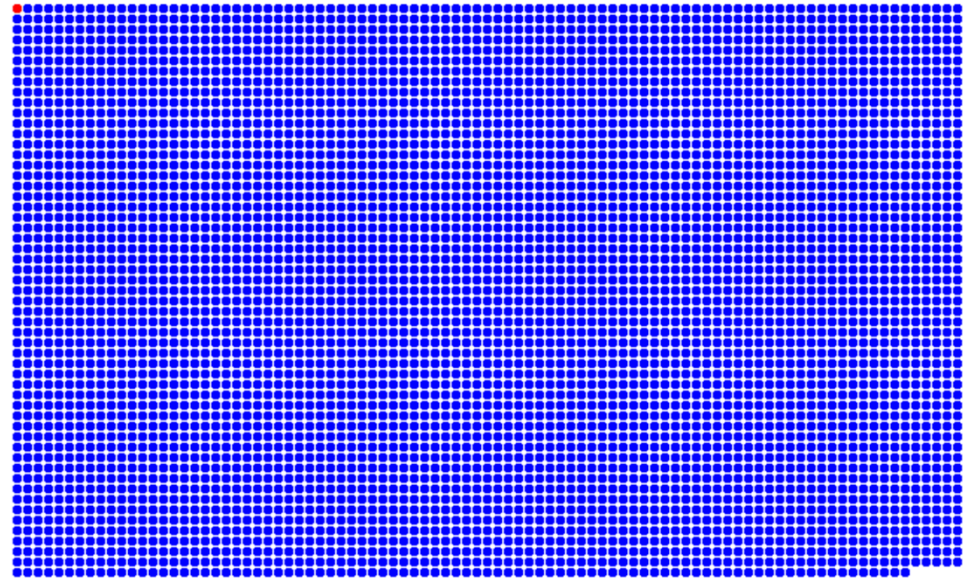
**Cost of oral elemental formula is a mortgage payment**

# EGID Incidence Rate

National Average – 1:2,000\*



Washington State – 1:5,000\*



\* Spergel, Jonathan M. et al., Variation in Prevalence, Diagnostic Criteria, and Initial Management Options for Eosinophilic Gastrointestinal Diseases in the United States, Journal of Pediatric Gastroenterology and Nutrition, 2010 Nov. 3 (Epub ahead of print), at 3.  
<http://www.ncbi.nlm.nih.gov/pubmed/21057327>

# How many people is 1:5,000?

## Safeco Field

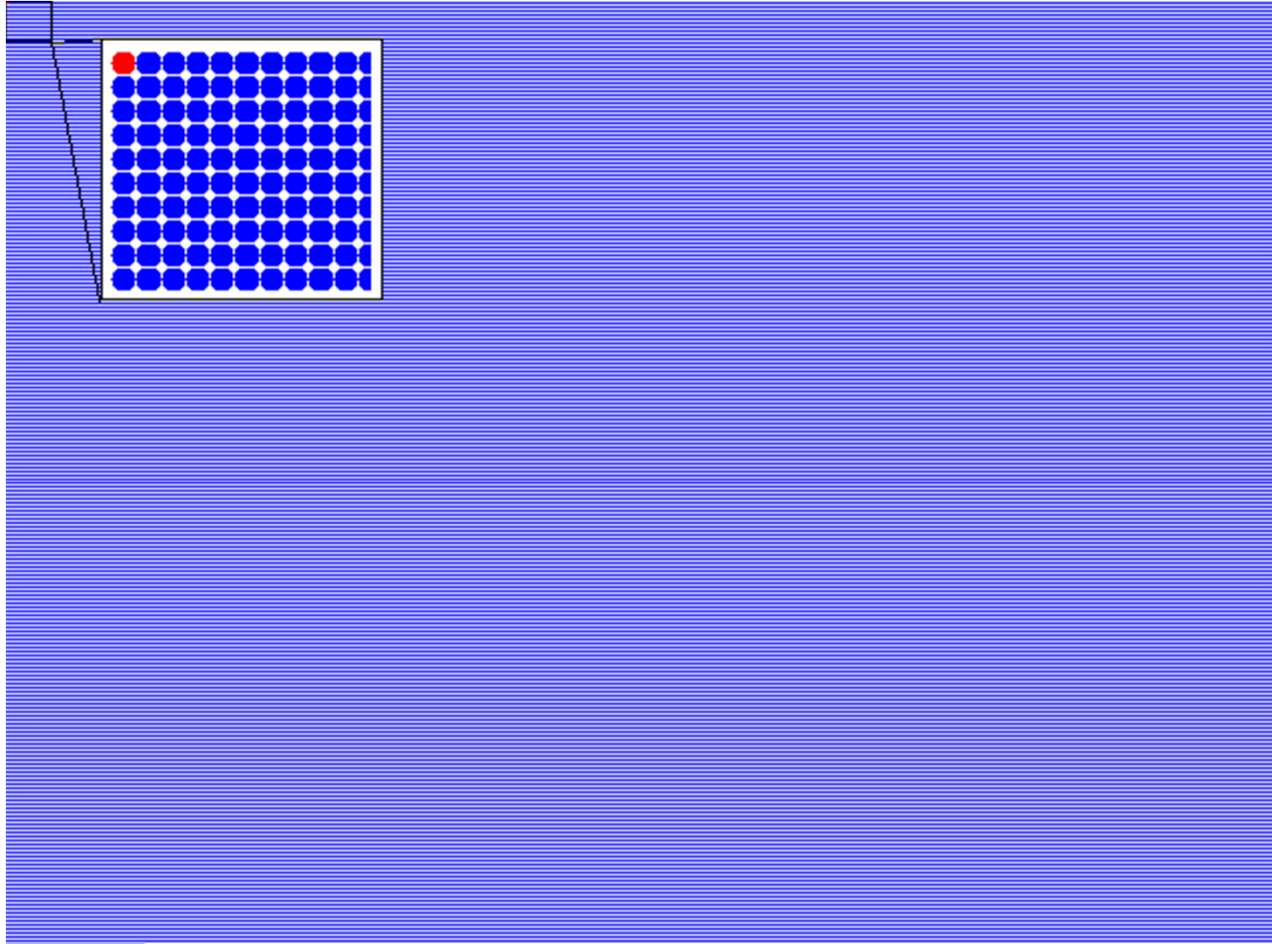
48,000 people capacity

~10 people with an EGID





# Acutely ill with an EGID – 1:30,000-1:75,000



NOTE: Only the acutely ill require medical food for treatment

# How many people is 1:30,000-1:75,000?

## Husky Stadium

75,000 people capacity

~1-2 person acutely ill  
with an EGID





# **Current state in Washington State**

# History within Washington State

1988 – Medical food coverage legislation enacted for the treatment of Phenylketonuria

2007 – EGID Legislation introduced in the Senate

- Not referred out of committee due to fiscal note

2009 – EGID Legislation introduced in the Senate

- Not referred out of committee due to fiscal note

2012 – Essential Health Benefits EGID advocacy

- No new health mandates

2013 – EGID Legislation introduced in the Senate and House

- Signed into law requesting this Sunrise review



# Washington State

6,897,012\* residents

~1,300 with an EGID

~100-200 acutely ill with an EGID

I know 40 EGID families



\*<http://quickfacts.census.gov/qfd/states/53000.html>

# Washington Insurance coverage for EGIDs

Women Infants Children (WIC) – NOT covered

Washington State Medicaid – covered

Washington State Health Insurance Pool (WSHIP) – covered

Essential Health Benefits – NOT covered

Public Employees Benefits Board – covered

Basic Health – covered

Federal Employees Health Benefits – covered

Private Insurance – Not consistent (most cover enteral only)

**Insurance coverage is confusing and not consistent**

# The path ahead

# What is needed?

**Insurance coverage for the treatment  
and diagnosis of Eosinophilic  
Gastrointestinal Disorders, regardless  
of delivery method (enteral or oral)  
and regardless of age**

# Potential Guide from other WA legislation: Oral Chemotherapy: HB 1517 - 2011-12

**An ACT Requiring comparable coverage for patients who require orally administered anticancer medication**

“The legislature finds that for cancer patients, there is an inequity in how much they have to pay toward the cost of a self-administered oral medication and how much they have to pay for an intravenous product that is administered in a physician's office or clinic.”

Enacted into law April 22, 2011

**Medical food coverage for the treatment of Eosinophilic Gastrointestinal Disorders**

Enteral feeding is 2-4x more expensive than oral

Policies commonly provide coverage for enteral feeding

# Potential Guide from other WA legislation: Diabetes Treatment: SB 5178 1997-98

## **An ACT Relating to the enactment of the diabetes cost reduction act**

“The legislature finds that diabetes imposes a significant health risk and tremendous financial burden on the citizens and government of the state of Washington, and that access to the medically accepted standards of care for diabetes... is crucial to prevent or delay the short and long-term complications of diabetes and its attendant costs.”

Enacted into law May 7, 1997

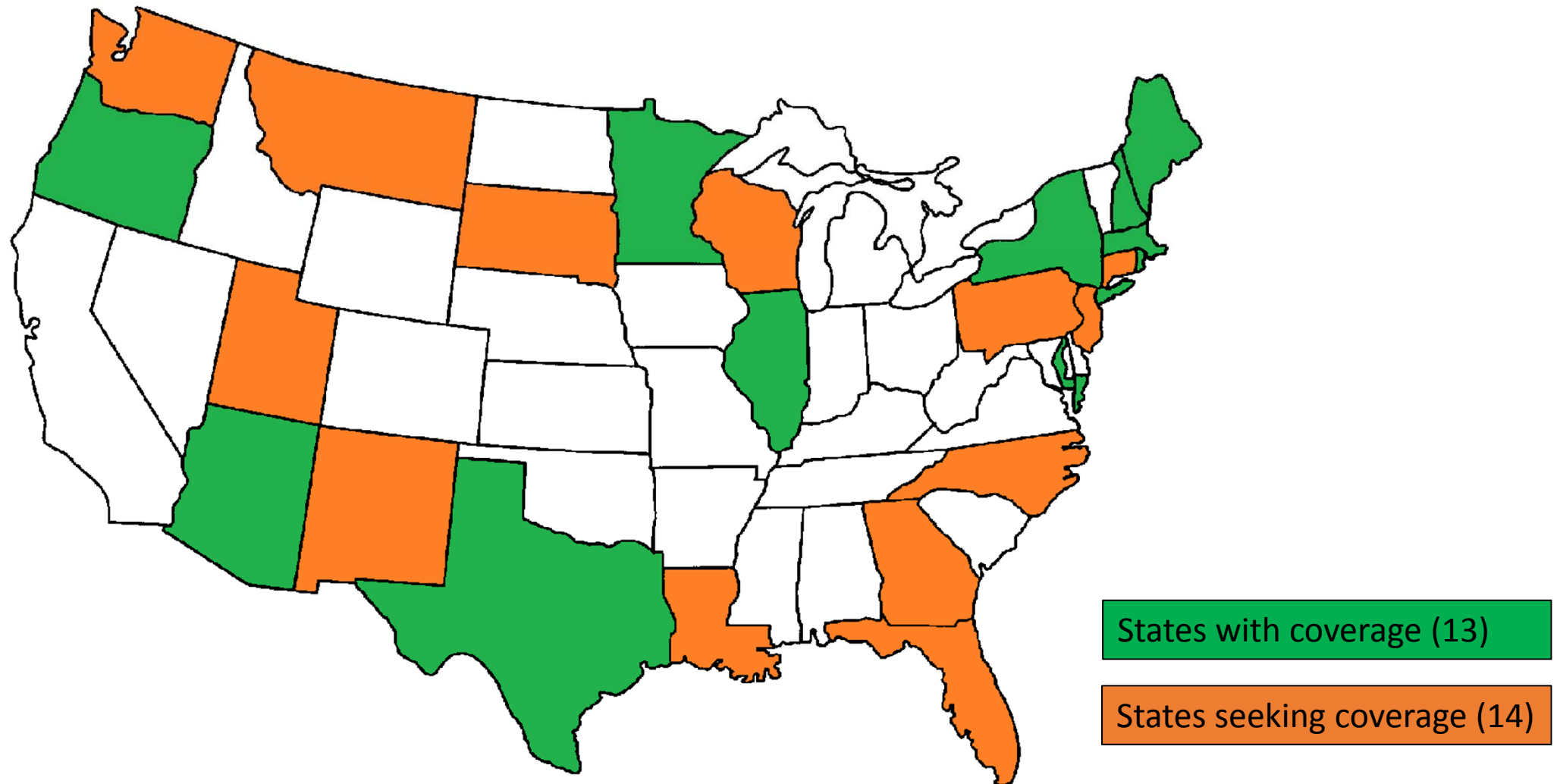
## **Medical food coverage for the treatment of Eosinophilic Gastrointestinal Disorders**

Medical foods are found to have 98% effectiveness

Out-of-pocket expense for oral feedings is >\$1,000 a month



# Coverage Across the Nation



# National / State Organizations



[Apfed.org](http://Apfed.org)



[curedfoundation.org](http://curedfoundation.org)



[empowerwa.blogspot.com](http://empowerwa.blogspot.com)



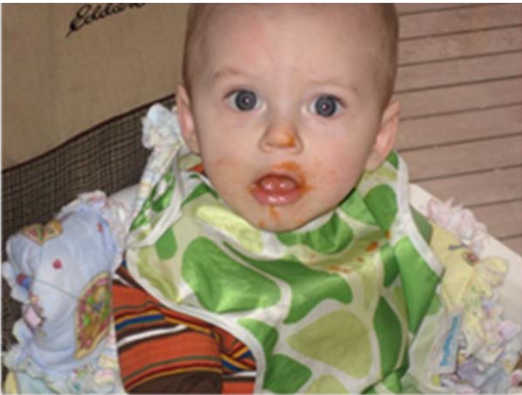
[Childrensmagic.org](http://Childrensmagic.org)

# Final thoughts

# Our story



3 months (14lbs 20oz)



6 months (13lbs 15oz)



Normally progressing 1 year olds food selection



Jacob's 1 year food selection

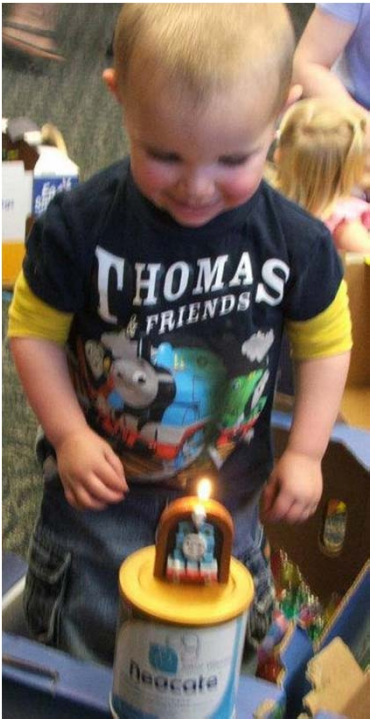


5 ½ years old (50lbs)



# Washington EGID Community

**“The cost is another mortgage payment”**



Connor



Jack and Sarah



Hayden and Chloe

**“When is the right time for insurance to cover a new disease?”**

**“The treatment is 98% effective!”**



**“There are two kinds of lucky – those that can eat food and those that have insurance coverage”**

# Sum it all up

Treatment is highly effective

Treatment cost is out of reach for most middle class families

Insurance coverage in Washington is confusing and not consistent

Very few people in Washington are impacted (~100-200 people would benefit)

**We need... Insurance coverage for the treatment and diagnosis of Eosinophilic Gastrointestinal Disorders, regardless of delivery method (enteral or oral) and regardless of age**

# Q&A





# Appendix F

## Hearing Follow Up



# Follow-up to the Sunrise Review: Eosinophilia Gastrointestinal Disorders Mandated Benefit Sunrise

Hearing Date – July 22, 2013

Author: Jeff Schwartz

## Introduction

This document intends to answer some of the questions asked during the Eosinophilic Gastrointestinal Disorder (EGID) Sunrise Review. The focus will be on the access to medical foods and their classification by the Food and Drug Administration (FDA).

Questions answered in this document:

- What are medical foods?
- What foods are designated as a medical food by the FDA?
- What is an elemental formula?
- What is Washington's current mandated coverage for medical food?

## Summary

To summarize, elemental formulas – also known as amino-acid based formulas – are classified as medical foods by the FDA and considered an Orphan Drug. A treatment option for those acutely ill with Eosinophilic Gastrointestinal Disorders is a specially produced medical food produced by Abbott Laboratories, Nutricia Advanced Medical Nutrition, Mead Johnson Nutrition, and Nestle Health Science.

The regulatory supervision for the distribution and manufacturing of medical foods is done by the FDA.

The State of Washington established medical food coverage for the treatment of Phenylketonuria (PKU) in 1988. This statute is narrowly written and as such Washington has not been adversely impacted – as far as I can tell – by the affordances for medical foods provided by the Orphan Drug Act (including over-the-counter access). In Washington medical foods are covered only for patients diagnosed with PKU and only for medical foods that treat PKU.

Similar to PKU, EGID medical food coverage can be narrowly written to only provide medical foods for patients diagnosed with EGIDs and only for medical foods that treat EGIDs.

## What are medical foods?

The FDA has the definitive answer on what constitutes a medical food. Attached to this document are CFR-2001-title21-vol2-part101 and Medical Foods Program – Import and Domestic which contain the definition and the regulatory requirements for medical foods.

The FDA is consistent in its classification of medical foods across the following points:

- Medical foods are specially formulated and processed products (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of patients
- Medical foods must be consumed or administered under the supervision of a physician
- Medical foods may be taken both orally and/or enterally
- Medical foods are Orphan Drugs and as such are afforded special leeway in distribution and regulation to help support research and development where a sufficient profit motivation may not exist

Below are two relevant excerpts from these documents.

### [CFR-2001-title21-vol2-part101](#)

Source: <http://www.gpo.gov/fdsys/pkg/CFR-2001-title21-vol2/pdf/CFR-2001-title21-vol2-part101.pdf>  
(page 34)

Summary: Medical foods classified under the Orphan Drug Act must be consumed or administered under the supervision of a physician, may be taken orally or enterally, and are specially formulated and processed products (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of patients.

#### Excerpt:

(8) Medical foods as defined in section 5(b) of the Orphan Drug Act (21 U.S.C.360ee(b)(3)). A medical food is a food which is formulated to be consumed or administered enterally **under the supervision of a physician** and which is intended for the **specific dietary management of a disease or condition for which distinctive nutritional requirements**, based on recognized scientific principles, are established by medical evaluation. A food is subject to this exemption only if:

(i) **It is a specially formulated and processed product** (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of **oral intake or enteral feeding by tube**;

(ii) It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;

(iii) It provides nutritional support specifically modified for the management of the **unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation**;

(iv) **It is intended to be used under medical supervision**; and

(v) **It is intended only for a patient receiving active and ongoing medical supervision** wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

## Medical Foods Program – Import and Domestic

Source: <http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm073339.pdf>

Summary: The Medical Foods coding 41G is for foods that are specially formulated and processed for the patient who is seriously ill or requires the product as a major treatment modality. Given the critical need for safe medical foods the FDA is committed to assuring their continued safety and integrity through annual inspections of all medical foods manufacturers in the U.S. and foreign countries.

### Excerpt:

The term "medical food" is defined in the Orphan Drug Act Amendments of 1988 [21 USC 360ee (b)(3)]. This definition was incorporated by reference into the Nutrition Labeling and Education Act (P.L. 101-535) in November 1990. It is incorporated into the agency's final rule on mandatory nutrition labeling published in January 1993. \*The definition of a medical food is a food which is formulated to be consumed or administered enterally **under the supervision of a physician** and which is **intended for the dietary management of a specific disease or condition** for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. (See 21 CFR 101.9(j)(8)).\*

Generally, to be considered a medical food, a product must, at a minimum, meet the following criteria:

- a) The product is a food for **oral or tube feeding**;
- b) The product is labeled for the **dietary management of a medical disorder, disease, or condition**; and
- c) The product is labeled to be used **under medical supervision**, and is **primarily obtained through hospitals, clinics, and other medical and long term care facilities**.

**Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods are to be used under medical supervision.** The term "medical foods" does not pertain to all foods fed to sick patients. **Medical foods are foods that are specially formulated and processed** (as opposed to a naturally occurring foodstuff used in its natural state) for the patient who is seriously ill or who requires the product as a major treatment modality. Typical medical foods are enteral nutrition products, i.e., products provided through the gastrointestinal tract, taken by mouth, or provided through a tube or catheter that delivers nutrients beyond the oral cavity or directly to the stomach.

...

Because of the susceptible population for which medical foods are intended, the agency is committed to assuring their continued safety and integrity through annual inspections of all medical foods manufacturers in the U.S. and foreign countries.

...

The following new product codes have been established and are currently in effect for coding medical foods.

Industry 41—Dietary Conventional Foods and Meal Replacements

41G Medical Foods (foods that are specially formulated and processed for the patient who is seriously ill or requires the product as a major treatment modality)

## Orphan Drug Act

Source: <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/SignificantAmendmentstotheFDCAAct/OrphanDrugAct/default.htm>

Summary: Orphan Drugs Act was established to reduce the costs of developing such drugs and to provide financial incentives to develop such drugs.

### Excerpt:

Orphan Drug Act – Excerpts (Public Law 97-414, as amended)

#### CONGRESSIONAL FINDINGS FOR THE ORPHAN DRUG ACT

The Congress finds that---

- (1) there are many diseases and conditions, such as Huntington's disease, myoclonus, ALS (Lou Gehrig's disease), Tourette syndrome, and muscular dystrophy which **affect such small numbers of individuals residing in the United States** that the diseases and conditions are considered rare in the United States;
- (2) adequate drugs for many of such diseases and conditions have not been developed;
- (3) **drugs for these diseases and conditions are commonly referred to as "orphan drugs";**
- (4) because so few individuals are affected by any one rare disease or condition, a pharmaceutical company which develops an orphan drug may reasonably expect the drug to generate relatively small sales in comparison to the cost of developing the drug and consequently to incur a financial loss;
- (5) there is reason to believe that some promising orphan drugs will not be developed unless changes are made in the applicable Federal laws to reduce the costs of developing such drugs and **to provide financial incentives to develop such drugs;** and
- (6) **it is in the public interest to provide such changes and incentives for the development of orphan drugs.**

## What foods are designated as a medical food by the FDA?

I was not able to find a recent list medical foods, as classified by the FDA. I believe this is a proprietary list maintained by the FDA which is not shared with the public. As potential evidence of this, the Medical Food Compliance Enforcement document had 2 attachments which were both removed before publishing publicly stating they are 'not for public distribution'.

<http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm073339.pdf>

Attachment A--List of known foreign medical foods manufacturers/shippers and their products  
**(Not for Public Distribution)**

Attachment B--List of exempt infant formulas (**Not for Public Distribution**)

### What is an elemental formula?

Elemental formulas are also referred to as amino-acid based formula and are classified as medical foods by the FDA. These formulas are hypoallergenic and made up of amino-acids – the amino-acids are the building blocks of protein and provide the necessary nutrition for a complete diet.

There are four common brands and manufacturers of elemental formula in the United States:

- Neocate – Nutricia Advanced Medical Nutrition (<http://www.nutricia-na.com/>)
- EleCare – Abbott Laboratories (<http://www.abbott.com/index.htm>)
- Nutramigen AA – Mead Johnson Nutrition (<http://www.meadjohnson.com/Pages/default.aspx>)
- Vivonex Pediatric – Nestle Health Science (<http://www.nestlehealthscience.com/>)

Below is an explanation of what differentiates an elemental formula from other formulas – including other formulas that are designed for food intolerance:

<http://www.neocate.com/about-neocate/breastfeeding-and-formulas/how-neocate-is-different/>

	Protein Structure in Infant Formulas	Type of Protein	Formulas Available*	Hypo-allergenic	Contains Milk Proteins (Whey or Casein)	Protein Type
		Dairy and soy-based	Enfamil Lipil <sup>®1</sup> Smilac Advance <sup>®2</sup> ProSobee <sup>®1</sup>	No	Yes	Complete protein chains that can trigger an allergic reaction.
		Partially Hydrolyzed	Gentlease <sup>®1</sup> Good Start <sup>®3</sup>	No	Yes	Protein chains are partially broken down into pieces.
		Extensively Hydrolyzed	Nutramigen <sup>®1</sup> Alimentum <sup>®2</sup> Pregestimil <sup>®1</sup>	Yes	Yes	Protein chains are broken down into pieces. Although these formulas are called hypoallergenic, they can still trigger an allergic reaction.
		Amino acid-based	<b>Neocate<sup>®</sup> Infant</b> (100% amino acid-based)	Yes	No	No intact protein chains, based on individual, non-allergenic amino acids. No peptide links to trigger an allergic reaction.

\*Examples – not a complete list

<sup>1</sup>Mead Johnson Nutrition

<sup>2</sup>Abbott Nutrition

<sup>3</sup>Nestle Nutrition

## What is Washington’s current mandated coverage for medical food?

The State of Washington currently mandates coverage for medical foods for the treatment of Phenylketonuria (PKU).

Critical note – The treatments for PKU and EGIDs are different and I am not trying to equate the disorders, though the treatment for PKU and EGIDs both benefit from medical foods, so there is a potential corollary in how to effectively mandate coverage for medical foods.

RCW 48.20.520, 48.21.300, 48.44.440, and 48.46.510 establish coverage for medical foods for the treatment of PKU: established in 1988.

- <http://apps.leg.wa.gov/RCW/default.aspx?cite=48.20.520>
- <http://apps.leg.wa.gov/RCW/default.aspx?cite=48.21.300>
- <http://apps.leg.wa.gov/RCW/default.aspx?cite=48.44.440>
- <http://apps.leg.wa.gov/RCW/default.aspx?cite=48.46.510>

Based on a document by Mead Johnson Nutrition ([http://www.meadjohnson.com/documents/specialized\\_feeding\\_solutions\\_fact\\_sheet.pdf](http://www.meadjohnson.com/documents/specialized_feeding_solutions_fact_sheet.pdf)), who manufactures a small number of products that treat metabolic disorders like PKU, these medical foods are granted the same affordances by the FDA as would medical foods used for the treatment of EGIDs. A concrete example that was brought up at the Sunrise Review hearing is that these medical foods are also available over the counter (OTC) as are all medical foods. An internet search for ‘Phenyl Free 1’ showed that it could be purchased online – though like all medical foods, it is explicitly formulated to be administered under the supervision of a physician.



# Appendix G

## Rebuttals to Draft Report



## Rebuttals to Draft Report September 10, 2013

I fully support the DOH's findings that "the proposal's concept is in the best interest of the public and that the benefits outweigh the costs of covering amino acid-based elemental formulas for treating EGIDs" and the three recommended changes to the draft bill.

I do not have any recommended changes to the proposal as written.

Thank you and the DOH for your consideration and detailed research it took to make this proposal.

If you need any additional assistance as you work through the rebuttal period or approval process, please do not hesitate to ask.

Jeff Schwartz

---

First of all thank you for your efforts on behalf of EGID patients and their families.

In case you are not aware, below are additional Eosinophilic disorders:

1. Eosinophilic asthma,
2. Eosinophilic fasciitis,
3. Eosinophilic lung disorders,
4. Eosinophilic pneumonia,
5. Eosinophilic leukemia, and
6. Hyper-eosinophilic syndrome.

As I mentioned in my earlier correspondence, my son's Eosinophilic Esophagitis (EoE) triggered at the age of 23. He has improved some now; however, when his EoE first triggered one year ago, he lost a total of approx. 70 pounds (5 pounds a week) and became severely malnourished.

### **EOE PATIENTS FACE A VARIETY OF ISSUES IN REGARDS TO FOOD:**

**Severity of Allergies:** There are varying degrees of allergies/tolerances to foods.

**Metabolic Rate:** For my son, some type of formula is necessary--even though he has gained some weight. He is 6'2" and now weighs approx. 140 pounds. However, his metabolic rate is high, and even though he intakes approx. 1200 calories a day now, he cannot gain weight. [Note: His dietician and allergist recently instructed him to take Neocate Jr., but it is expensive and he hasn't found one he can tolerate yet, but he keeps testing them. Kaiser recently told us they would not cover the cost of the Neocate Jr. even knowing if he cannot gain weight,

he cannot work out, which is bad for his general overall health, his diabetes, and for him his pain from Ehlers-Danlos which greatly intensifies from the lack of muscle and results in multiple bone dislocations. Due to his severe pain, he is on prescription painkillers, which can lead to addiction.]

**Exercise Requires Additional Calories:** In addition, if he began to exercise, he would lose even more weight.

**Loss of Tolerance of Portions of Food:** It should be noted that after living on a liquid diet for multiple months, it takes time to build up the physical ability to tolerate more solid foods and larger portions. My son also suffers from the loss of the feeling of being hungry, so he needs to currently remind himself to eat.

**Physical Limitations:** Stitures, upset stomachs, throat closure, food impaction, etc.

**Impact of Other Possible Underlying Conditions:** Now he needs to gain weight, but due to his EoE food allergies combined with being a Type 1 Diabetic, he has not been very successful. His body's allergies also reacted negatively to TPN and some formulas. In addition, EoE patients are more likely than the general public to also suffer from a connective tissue disorder, which he does. Possibly due to Ehlers-Danlos Syndrome, he also suffers from issues with vibrations (e.g. riding in vehicles).

**Psychological/Other Limitations:** Fear of eating due to impaction, upset stomach, allergic reactions, fear of getting sick again, sick of eating the same exact foods (some of which don't even taste good) all the time, how friends/family respond to your diet, depression from long term illnesses, etc. Due to the medical community not being aware of EoE, or not being able to physically "see" your throat closure, they can believe you suffer from a mental disorder and therefore not address the real physical problem, which would have killed my son if I hadn't done my own research. Until they figure it out, this can lead to frustration, additional suffering, embarrassment, lack of faith in the medical community, etc.

**Cost of Food/Medicine/Medical:** Foods that can be tolerated are found through a trial and error process which creates a large amount of waste and expense. Organic foods, gluten free foods, etc. are generally more expensive than regular food.

In addition, we have heard many patients, who could benefit from Cromolyn (medication), are not able to take it because it is expensive and many insurances do not cover the prescription.

#### DISABILITY:

STATE DISABILITY: Since he is an adult, there appears to be fewer financial programs/benefits available to him, and those that are available appear to be more difficult to qualify. For example, his initial six months of California state disability was not approved due to the fact he did not work in the previous calendar year (because he was in college)..even though he worked during the year he became sick and had paid in the required amount. Many young

people, due to college etc., may not qualify at all for benefits if they do not work or do not earn enough money. My understanding is minors qualify automatically under their parents.

**SOCIAL SECURITY DISABILITY:** In addition, for Social Security Disability, EoE should be on their list of automatically approved disabilities. This is a "chronic" disorder and even if it is brought under control, it oftentimes reoccurs again. My son, who has a severe case of EoE-CTD (CTD referring to a connective tissue disorder, more specifically Ehlers-Danlos Syndrome-- which causes intense pain throughout the body), suffers from a multitude of food allergies including gluten, and everything environmental, and molds. Due to the airborne components (including molds) of his allergies, it is not possible for him to "eliminate" them completely.

Cindy Nickel