

CHILDREN'S MAGIC

MILK ALLERGY AND GASTROINTESTINAL COALITION

Statement for the Pennsylvania House Children and Youth Committee

Overview:

The Children's Milk Allergy and Gastrointestinal Coalition (CM) is a non-profit organization devoted to assisting families in their struggle for coverage of amino acid based formulas. It is composed of parents, patients, healthcare providers, corporations and other like-minded individuals. We are writing at this time to regarding a serious issue facing some families in the state of Pennsylvania.

Our concern is that there are approximately 1,042 children with food allergies in Pennsylvania who require amino acid based elemental formulas to meet their nutritional needs. We are concerned further that these 1,042 PA infants and children with private insurance cannot routinely get coverage for these formulas (Exhibits 1,1a Insurance policies, Ex 2. Email copies to CM). This issue does not affect children in the state covered by Medicaid & WIC because PA Medicaid & WIC does provide coverage for these formulas.

Before we discuss this matter in-depth, we would like to provide a brief nutritional primer on the importance of milk in a child's diet.

- Milk, contains all of the essential amino acids children need for growth and development.
- Protein (an amino acid) is needed to build and repair body tissues and form antibodies which fight infection.
- Milk also contains calcium necessary to build strong teeth and bones and good brain tissue.
- It would take large amounts of vegetable servings to get the same amount of calcium in 2 or 3 glasses of milk.

What is the problem?

The problem is that some children are allergic to milk. In particular they are allergic to the casein protein found in cow's milk and soy milk. Even worse is the fact that some children are allergic to almost all foods. Children with food allergies that require these formulas can be broken down into 2 primary categories:

1. Children allergic to the proteins found in milk (approximately 974 PA infants and toddlers). The American Academy of Pediatrics indicates that children allergic to Cow's milk are most often also allergic to soy milk. Rice milk while low in allergens is not nutritionally complete, meaning it does not have the nutrients necessary to provide normal growth and development in children. Symptoms vary by child but can include stomach pain, skin rashes bloody stool (ex.3, 3a. Milk Allergy w/ Skin Rash).

2. Children with a condition entitled Eosinophilic Esophagitis (EOE) who are allergic to almost all foods (approximately 537 PA children). For unknown reasons their bodies see food as a foreign agent and sets up defenses to fight within their digestive tracks. Symptoms include severe stomach pain, vomiting, difficulty swallowing to the point insertion of a tube into the stomach is required. These children often undergo an elimination diet, meaning all foods are removed and re-introduced one by one to determine which foods will not produce an allergic reaction. During this time, amino acid based formulas are their only source of complete nutrition. Moreover some children with EOE remain allergic to most foods and are only able to consume a few fruits.

There are no medications to make the children above not allergic to milk or to other foods. There is no other way for infants and toddlers to get the nutrients they would normally get from milk. There is also no other way for older children to get the nutrients they would normally get from meats, vegetables, fish and fruits.

What is amino acid based elemental formula and how does it help?

First, amino acid-based elemental formulas are prepared from individual (single) non-allergenic amino acids different from regular dairy (milk or soy based) formulas and foods that include numerous complete proteins linked together as a chain. Amino acid-based elemental formulas are made of proteins broken down to their "elemental level" (simplest, purest, singular form) making them easy to absorb and digest by the body. Amino acid based formulas have been engineered to strip out the allergy causing proteins found in regular milk but at the same time retain other non allergic proteins and vital nutrients such as calcium, vitamins A,D and B12, potassium, magnesium phosphorous, and riboflavin. They are nutritionally complete.

Secondly, amino acid based elemental formulas have been designated by The Food and Drug as "exempt" medical foods. According to the FDA, to be considered a medical food, a product must, at a minimum, meet the following criteria: the product must be a food for oral or tube feeding; the product must be labeled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and the product must be intended to be used under medical supervision. (See Exhibit 4, 4a, 4b FDA Formula and Medical Food citations, Infant Formula Label)

Why are we here?

Based on what has been presented today by parents and the physicians who treat them, it should be clear that these are not regular infant formulas. The FDA has classified them as formulas used to treat medical conditions, yet the insurance companies routinely deny their coverage (exhibits 1,1a) when prescribed by physicians to treat the conditions above.

Due to the technology necessary to strip out the allergic proteins, these formulas are more expensive than regular cow's milk based formulas (i.e., Similac/Enfamil). The annual cost of regular infant formula is around \$2K per year. The cost of amino acid based elemental medical formula can be as much as \$5K a year, or higher (depending where the formula is purchased and how much a child eats).

We are here because families with private insurance and children who need these medical formulas are paying health insurance premiums monthly, and they are paying for medical formulas. Moreover, in addition to the nightmare of having a sick child, they are forced to fight with their insurance company for the only thing that will help their child.

How Many Pennsylvania Children Are Affected?

Nationally, 90% of all food allergies are related to one of the following foods: milk, eggs, peanuts, soy, wheat, fish, and shellfish.

The Data Resource Center for Child & Adolescent Health produces state specific information on Children With Special Healthcare Needs by condition (including food allergy). This well known data source indicates there are 38,945 children in the state of Pennsylvania with food allergies to food sources such as those listed above (ex. 5). Our research indicates that 2% of infants and children are specifically allergic to milk (exhibit 6,6a). Therefore 2% or 974 of the 38,945 children in PA with food allergies are allergic to milk. Further research reveals that the prevalence of EOE is 28/100,000 or 537 children in PA. Based on these published statistics, we estimate the total number PA children needing these formulas to be 1,510; however Census Bureau statistics indicate that 31% of PA children (468) are covered by Medicaid who does already provide coverage/payment for these formulas. That would leave 1,042 children covered by private insurance that would potentially need formula.

What is the cost to the Insurers?

Insurance companies calculate and express cost on a per member per month (PMPM) basis. For example, The American Academy of Pediatrics "Pediatric Cost Model" for PA indicates that commercial insurers paid \$498,232,000 or \$14.78PMPM (when spread across the PA commercial insurance population) for pediatric office visits. Utilizing the same pmpm cost calculation/expression, \$3K in formula cost spread across the PA commercial insurance population would yield a cost of 3cent per member per month (3cent/PMPM). At the higher end of cost, \$5K spread across the same private insured population would yield a cost of 5c per private insured member per month (5cent/PMPM).

What is our ask?

In addition to helping the families here today, Children's MAGIC asks that you help all of the 1,042 PA families with children who suffer from food allergies and require amino acid based formulas to survive and thrive. The families of the 1,042 PA children requiring these medical formulas who pay an average \$2,328 per year in insurance premiums are asking the insurance companies to pay 3-5 pennies.

Children's MAGIC urges this Committee to support PA HB 49 and 1436.

[Ex 3] BEFORE AMINO AND BROAD FORMULA



[E_h 3a] AFTER Amino Acid BASED FORMUL



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Clinical Policy Bulletin: Nutritional Support

Number: 0061
(Replaces CPB 144)

Policy

Notes:

- I. For members with such a plan benefit, specific nutritional support is considered to be a medical item *only* when it is administered enterally (i.e., by feeding tube) or parenterally (i.e., by intravenous administration) where the member has either (a) a permanent* non-function or disease of the structures that normally permit food to reach the small bowel; or (b) disease of the small bowel that impairs digestion and absorption of an oral diet, either of which requires enteral or parenteral feedings to provide sufficient nutrients to maintain weight and strength commensurate with the member's overall health status. Note: Not all benefit plans cover nutritional support even in the circumstances stated above. Please check benefit plan descriptions.
- ✦ II. Aetna does not cover nutritional support that is taken orally (i.e., by mouth), unless mandated by state law. Oral nutrition is not considered a medical item. See section on Special Medical Foods below.
- III. Regular food products are not considered medical items. Regular food products include food thickeners, baby food, gluten-free food products, high protein powders and mixes, low carbohydrate diets, normal grocery items, nutritional supplement puddings, weight-loss foods and formula (products to aid weight loss), or other regular grocery products that can be mixed in blenders and used with an enteral system regardless of whether these regular food products are taken orally or parenterally.

Determinants of the route of administration of nutritional support include the functional status of the gastrointestinal tract and the anticipated duration of therapy.

I. Enteral Tube Feedings

Policy History

> [Last Review](#): 02/25/2014
Effective: 10/20/1995
Next Review: 01/22/2015
> [Review History](#)
> [Definitions](#)

Additional Information

> [Clinical Policy Bulletin Notes](#)

Highmark Medical Policy Bulletin

Section:	Orthotic & Prosthetic Devices
Number:	O-6
Version:	015
Topic:	Enteral Nutrition
Effective Date:	September 2, 2013
Issued Date:	September 2, 2013
Date Last Reviewed:	04/2013

General Policy Guidelines

Indications and Limitations of Coverage

Effective June 20, 1997, enteral feeding solutions (enteral formulas, procedure codes B4157, B4162, B9998) administered by any method are eligible when necessary for the therapeutic treatment of the following hereditary genetic disorders as defined in Act 191 - 1996. Under this Act, benefits for medically necessary enteral formulas, such as PKU 1 or 2, Lofenalac, or Ketonex 1 or 2, administered under the direction of a physician for these specified conditions are exempt from any contract deductibles:

- Phenylketonuria (PKU)
- Branched-chain ketonuria
- Galactosemia
- Homocystinuria

Infant formulas, administered either by mouth or through a tube, may be considered medically necessary based on the content of the formula and the reason for use of a special formula as noted above. Lactose intolerance, milk protein intolerance, or other milk allergies are not indications for coverage and therefore considered not medically necessary. However, any hemorrhagic colitis secondary to these conditions is medically necessary. It will be necessary for the provider to submit medical records and/or additional documentation to determine coverage in this situation. ←

Enteral feeding via nasogastric, jejunostomy, or gastrostomy tubes is an alternative to parenteral nutrition for the patient with a functioning gastrointestinal tract but for whom regular, oral feeding is impossible. Indications for enteral feeding solutions (enteral formulas, procedure codes B4149-B4155, B4158-B4161) via tube feeding include but are not limited to:

- Catheter sepsis from hyperalimentation
- Central nervous system diseases
- Fistula
- Gastrointestinal cancer
- Granulomatous colitis
- Head and neck cancer and reconstructive surgery
- Infection, chronic
- Intestinal atresia (infants)
- Irradiated bowel
- Ischemic bowel disease
- Jaw fracture
- Malabsorption syndrome
- Obstruction of gastric outlet due to ulcer diathesis
- Pancreatitis, acute or chronic
- Partial obstruction
- Renal failure
- Short-gut syndrome
- Stroke
- Ulcerative colitis, acute

ELECTRONIC CODE OF FEDERAL REGULATIONS**e-CFR Data is current as of March 12, 2014**

Title 21: Food and Drugs
PART 107—INFANT FORMULA

Subpart A—General Provisions

Contents

§107.1 xxx

§107.3 Definitions.


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Link to an amendment published at 79 FR 8074, Feb. 10, 2014.

[⬆ Back to Top](#)**§107.3 Definitions.**

Link to an amendment published at 79 FR 8074, Feb. 10, 2014.

The following definitions shall apply, in addition to the definitions contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act):

Exempt formula. An exempt infant formula is an infant formula intended for commercial or charitable distribution that is represented and labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems. 

Manufacturer. A manufacturer is a person who prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of an infant formula or packages the infant formula in containers for distribution.

References. References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[50 FR 48186, Nov. 22, 1985]

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Food

Medical Foods Guidance Documents & Regulatory Information

The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) 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." ←

- Draft Guidance for Industry: Frequently Asked Questions About Medical Foods; Second Edition¹
- Medical Food Compliance Program - Import and Domestic (PDF 172KB) ²

Page Last Updated: 08/21/2013

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Links on this page:

1. [/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/ucm054048.htm](#)
2. [/downloads/Food/ComplianceEnforcement/UCM073339.pdf](#)

[Ex.5]

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Data Resource Center for Child & Adolescent Health

2009/10 NS-CSHCN: Condition-Specific Profile

Pennsylvania

Allergies (food only)

[Return to Snapshot Selection](#)[Return to Indicators Selection](#)[Return to Conditions Selection](#)

Part I: % of CSHCN with Allergies (food only) ←

% of CSHCN overall with condition: 8.5
 Estimated number with condition: 38,945 ←

% of CSHCN with Condition

By Age Group

	Pennsylvania
0 - 5 years	9.9
6 - 11 years	5.0
12 - 17 years	11.2

By Sex

	Pennsylvania
Male	8.7
Female	8.2

% of CSHCN with Condition

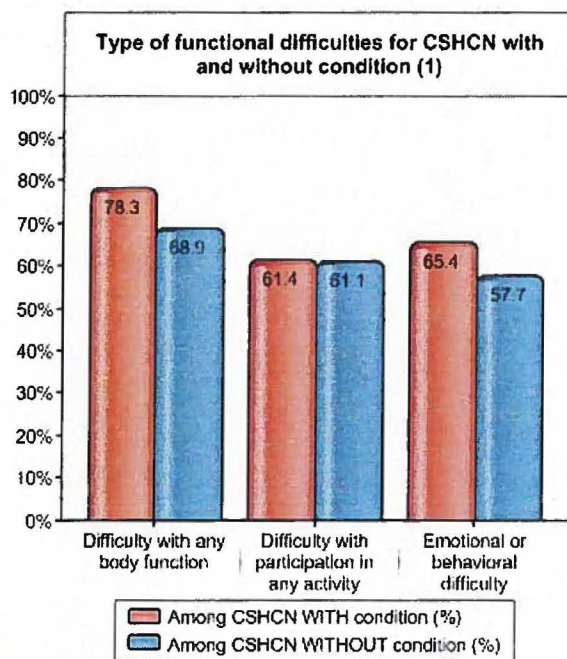
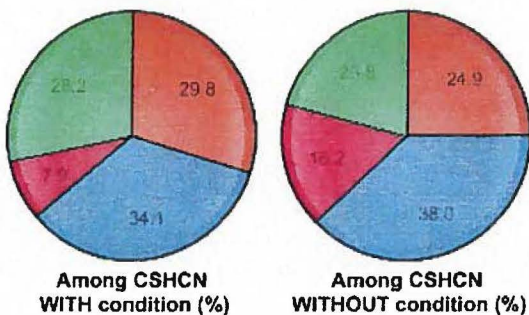
By Insurance

	Pennsylvania
Private insurance only	9.6
Public insurance only	5.8
Both public and private	10.9
Uninsured	1.6

By SSI Status

	Pennsylvania
Receives SSI for disability	2.8

Part II: Selected Health Characteristics among CSHCN with Allergies (food only) -- PENNSYLVANIA

**% of CSHCN with and without condition qualifying on specific types of special health needs criteria (2)**

Number of health conditions from list of 16 asked

None on list

Among CSHCN WITH condition (%)

0.0

Among CSHCN WITHOUT condition (%)

10.9

Number of functional difficulties from list of 14 asked

None on list

Among CSHCN WITH condition (%)

5.8

Among CSHCN WITHOUT condition (%)

9.9



Cow's milk allergy: prevalence, symptoms and diagnosis

Prevalence

→ Milk allergy is estimated to affect 2% of infants and young children in the UK population.

The prevalence of CMA varies with age, with highest prevalence in early childhood (2-6%) and decreasing prevalence with increasing age.

The incidence in adulthood is just 0.1-0.5%.

Individuals with a family history of allergy or genetic predisposition are more susceptible to develop CMA.

Of the 8 most prevalent food allergies, cow's milk allergy is the most common amongst infants.

It usually develops early in infancy when susceptibility is highest and soon after exposure to cow's milk infant formula.

Onset after 12 months is rare and the risk of developing CMA is reduced by exclusive breastfeeding, but this may not prevent the risk altogether.

Unfortunately high levels of self-diagnosis lead to exaggerated claims and rates of allergy incidence.

In fact a study in Australia showed self-diagnosis in an Australian population to be 10 times higher than true incidence following clinical diagnosis.

The prognosis of CMA is good, with remission rates of about 45-50% at 1 year of age, 60-75% at 2 years and 85-90% at 3 years. This means 9 out of 10 sufferers will grow out of the allergy by the age of 3.

The allergy is most likely to persist in those with a strong family history of allergy especially other food allergies such as to eggs, soya, peanuts or citrus fruits.

Symptoms

Symptoms of IgE mediated reactions include one or more of the following:

- Skin problems such as eczema, urticaria, angioderma, dermatitis.
- Gastrointestinal problems such as nausea, vomiting, diarrhea.
- Respiratory problems such as wheezing, coughing, rhinitis, asthma.

Although extremely rare, anaphylactic reactions (severe and very rapid reactions) to cow's milk protein may also occur following contact with the mouth or lips.

Symptoms of non-IgE mediated reactions include: gastrointestinal problems such as nausea, bloating, intestinal discomfort and diarrhoea and respiratory problems

Anaphylactic reactions do not occur.

Diagnosis

Diagnosis of cow's milk allergy is difficult due to the wide range of possible symptoms that may occur.

It is important that reliable techniques are used to diagnose CMA in order to avoid unnecessary exclusion of cow's milk from the diet.

The generally accepted methods of diagnosing CMA include:

Skin tests: this involves using either a test lancet or needle, which is first pricked in the food and immediately afterwards in the skin. The value of this test is limited since it measures only IgE mediated reactions and thus

Histopathology of EGE
 Clinical Manifestations
 Image Diagnostic Techniques in EGE
 Treatment of EGE
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 Sidebar

impaction in young males and the second most common cause of chronic esophageal disturbance after gastroesophageal reflux disease.^[6] has increase the awareness and diagnosis of new cases of EGID. The disorder begins with a constellation of symptoms that depend on topography and the intensity of the inflammatory response, eventually leading to endoscopic evaluation of these patients.

This rise in the prevalence of EGID and immunologic diseases in general has occurred in parallel with a decrease in infectious diseases, a coincidence that has been explained through the hygienic hypothesis.^[7] This hypothesis asserts that reduced exposure to microorganisms during childhood can modify the patterns of gut microflora, leading to a change in the fine tuning of Th1, Th2 and T-regulatory responses. This gives rise to an imbalance of

the immune system and a predisposition for developing allergic and autoimmune disorders triggered by altered or missing innate immune cell activation. In fact, the influence of Th2 cells, which are important in the development of responses mediated by IgE, usually fades after the first 2 years of life in nonallergic individuals. This is possibly due to a secondary stimulation of Th1 responses after bacterial infections,^[8] a phenomenon which is limited in over-hygienic environments. Environmental exposure thus seems to be an important risk factor as genetic predisposition for developing EGID. For example, one US study recently demonstrated that the increased prevalence of EoE parallels that of bronchial asthma in common geographical areas, being higher in urban as compared with rural settings,^[9,10] as well as in cold climate zones compared with tropical and arid areas.^[11]

Except for EoE, available data about the epidemiology of EGID in general and EGE in particular are limited. Due to its low prevalence, most of accumulated knowledge on EGE comes from individual case reports and short case series. Because these methods lack systematization, it is impossible to establish well-based conclusions or even a consensus with regard to diagnostic criteria: the density of eosinophilic infiltration or its precise location in the layers of the wall of the digestive tract vary widely from one study to the other. Since a certain eosinophil count can form part of the normal histology of the stomach and small bowel walls, and because this can vary between different geographical areas,^[12] a commonly accepted diagnostic criteria for EGE has not yet been defined. Still, an increase in the prevalence of EGE could have existed in several settings during the last years. In fact, the number of studies on EGE referenced in PubMed in the last decade has doubled since the 1980s representing almost 40% of the overall available scientific information on the disease.

Reported cases of EGE show no predominance of individuals of any gender or race. Although it can affect all ages, the majority of cases occur in adults in the third to the fifth decades of life,^[12-14] with pediatric series also being described.^[16,17] While no accurate epidemiological estimations for EGE exist to date, an incidence of approximately one case per 100,000 inhabitants has been traditionally proposed.^[13,14] However, these figures have been recently updated after an American electronic survey which estimated an overall prevalence of 28 per 100,000 EGE or colitis.^[10] Most patients are diagnosed during an endoscopic examination for a variety of symptoms, usually abdominal pain or diarrhea. An internet database has been set up recently in order to register cases and further clarify many of the unknowns of the disease.^[13]

Finally, it must be taken into account that a better awareness of EGID (and of EGE in particular) by clinicians and pathologists forms the cornerstone of accurate diagnosis of the disorder, which may subsequently contribute to the rise in its epidemiology, especially in different parts of Europe.

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Date: Wed, 22 Jan 2014 21:11:39 -0500 [01/22/2014 09:11:39 PM EST]

From: Danielle I

To: info@childrensmagic.org <info@childrensmagic.org>

Subject: WV HB 3147

Show this HTML in a new window?

Hello, my name is Danielle I. I have been in contact with Victoria from the American Partnership of Eosinophilic Disorders. She wanted me to share my story with you all since there is current legislation presented to require insurance companies to pay for medically necessary formula for patients that have eosinophilic disorders. I reside in the state of WV. Below, is our story:

Our family is currently affected by having to pay out of pocket for medically necessary formula (Elecare, Jr) for our 1 year old son because our insurance won't pay for it. Jeremiah was diagnosed with Eosinophilic esophagitis (EoE) back in June 2013 and we fought for 4 months to finally be denied for the 3rd time. Prior to his diagnosis, he was very sick for 5 months which included over 20 doctors visits, and eventually led to severe malnutrition and a hospital stay of 9 days to get him back to the growing 1 year old he was. He was developmentally delayed and once he was placed on this formula at the hospital, he came home crawling (15 months). Without this formula, our son would not be able to survive.

One of the reasons we were told that they wouldn't pay for the formula was because he didn't have a feeding tube. Thankfully, our son can deal with EoE without having to be attached to a feeding tube. We are not sure how long he will have to have to this formula to continue to thrive, but we would like to have help from our insurance. Also, a frustration we have is knowing that those who qualify for WIC, which we don't qualify for, can go and get this, without doctor documentation of having medical issues to get Elecare, Jr.

If there is anything that would be helpful to get this bill passed, please provide any suggestions.

Thank you for your time,

Danielle I
Huntington, WV

Date: Tue, 28 Jan 2014 15:01:26 +0000 [01/28/2014 10:01:26 AM EST]

From: Casha L

To: info@childrensmagic.org <info@childrensmagic.org>

Subject: Formula for my child

Show this HTML in a new window?

Hi. My name is Casha. My son Braxton, who is 8 months old, recently got diagnosed with a rare immune disorder where he is allergic to all food protein. He is solely on PurAmino formula

(Amino-acid based), and may be on it for at least a year with the hope that he may someday out grow it. Our insurance was covering his formula at 100%, and just recently cancelled coverage because he is not tube fed. His formula will cost us almost \$4000 a year. My husband and I both have jobs so we do not qualify for WIC but can not afford to spend that much a month. We are fighting with our insurance to get it covered. Our pharmacy that supplies his formula is filling out a pre-authorization form with all his medical history from his specialists to submit to insurance. Insurance told us they would review his case. Is there anything else I can do to help our chances of getting his formula covered? Or do you know of any other services or programs that help with coverage? Any information you have will be appreciated.

Casha M

Date: Mon, 16 Dec 2013 11:28:24 -0800 [12/16/2013 02:28:24 PM EST]
From: Darlene C
To: info@childrensmagic.org <info@childrensmagic.org>
Subject: [No Subject]

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Hi

What recourse do I have if my insurance refuses to pay for this formula? I see under Massachusetts law elemental formula coverage it looks like they are required to cover it?? Not sure I understand or if that will help my cause with my insurance company which is Cigna. Thanks in advance for any help/suggestions/advice etc..

Darlene C

Date: Thu, 5 Sep 2013 14:47:07 -0700 [09/05/2013 05:47:07 PM EST]
From: jessica S
To: info@childrensmagic.org <info@childrensmagic.org>
Subject: Help with Ins company

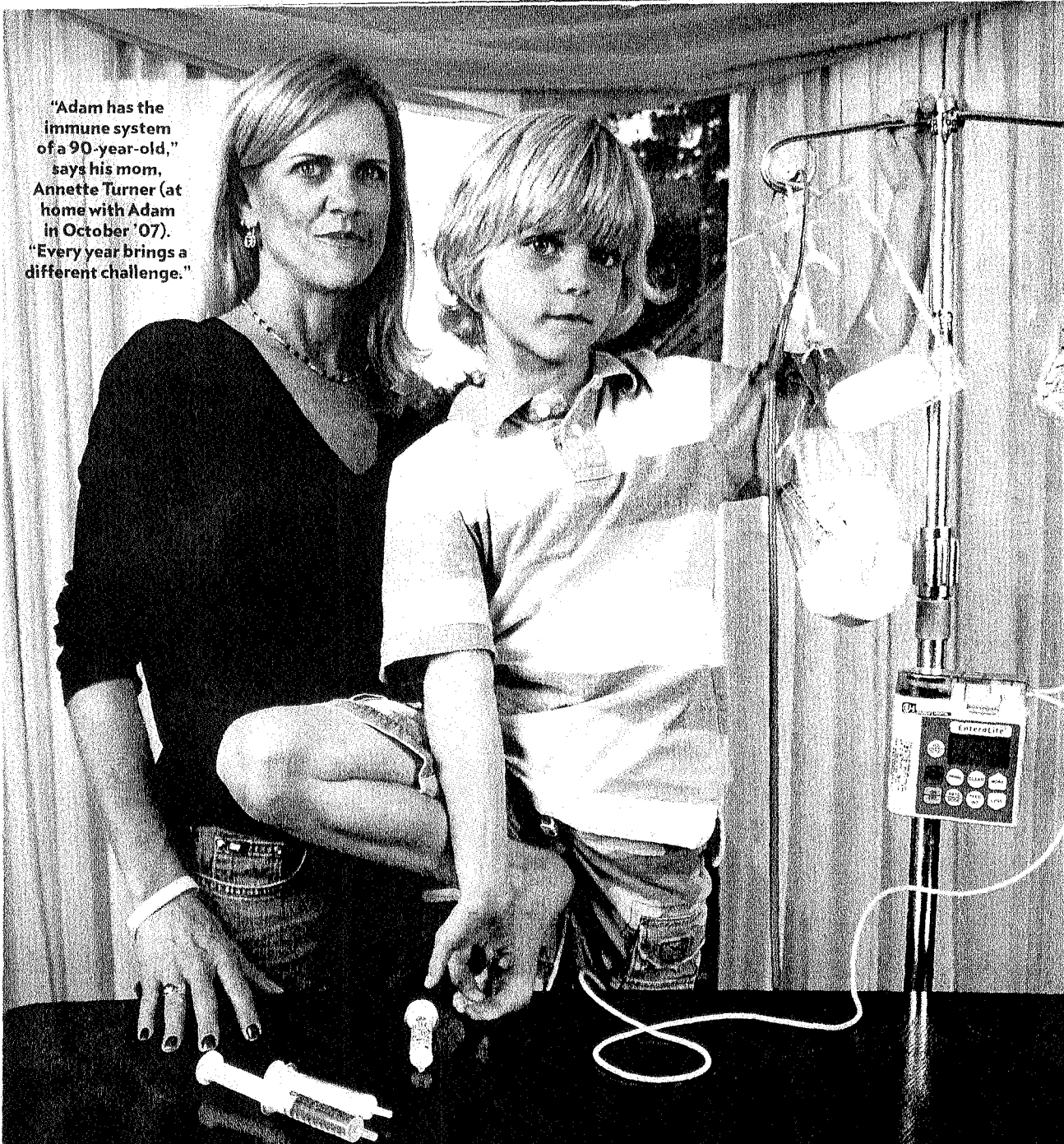
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Hello,

I just came across your website while looking for help to cover our newborns PurAmino formula. We have been fighting with both of our insurance companies for over a month now with no avail. . .do you have any tips/tricks to help get the amino acid formulas approved? Both companies keep telling myself, pediatrician office and GI Dr office that it is available over the counter and that is why it is not covered. Which it is not. . . Any help you can provide would be GREATLY appreciated!!

Thanks in advance for your help!

Jessica



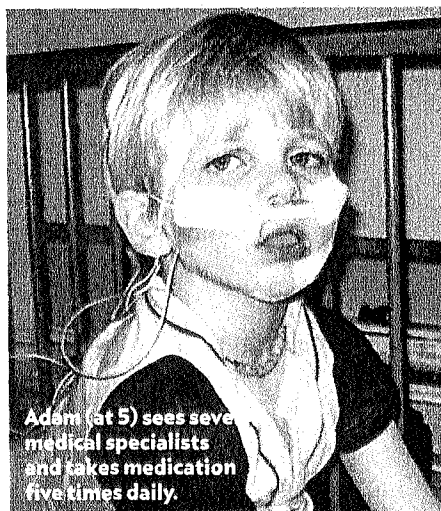
"Adam has the immune system of a 90-year-old," says his mom, Annette Turner (at home with Adam in October '07). "Every year brings a different challenge."

THE BOY WHO COULDN'T EAT

Mealtimes used to be torture for Adam Turner, who is allergic to nearly every kind of food. But this feisty second-grader has a huge appetite for life

BY JILL SMOWE

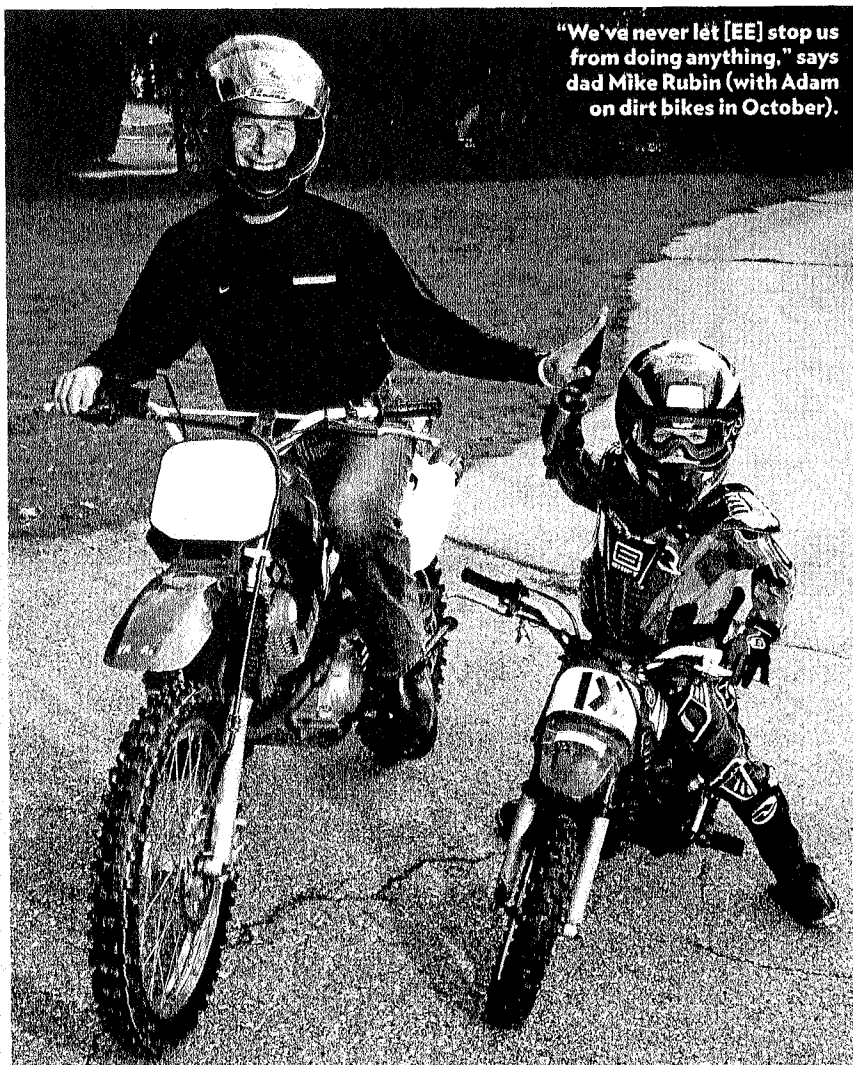
On Adam Turner's 7th birthday, he blew out the candles on a soccer cake, then looked on as his friends devoured their slices. Last year he insisted on opening an electronic lunch account at school,



Adam (at 5) sees severe medical specialists and takes medication five times daily.



"He's totally fearless," Rubin says of Adam (on skis at 5).



"We've never let [EE] stop us from doing anything," says dad Mike Rubin (with Adam on dirt bikes in October).

each day typing his PIN number into the keypad but buying nothing. And at Halloween, dressed as a surfer, he collected candy but didn't touch a piece.

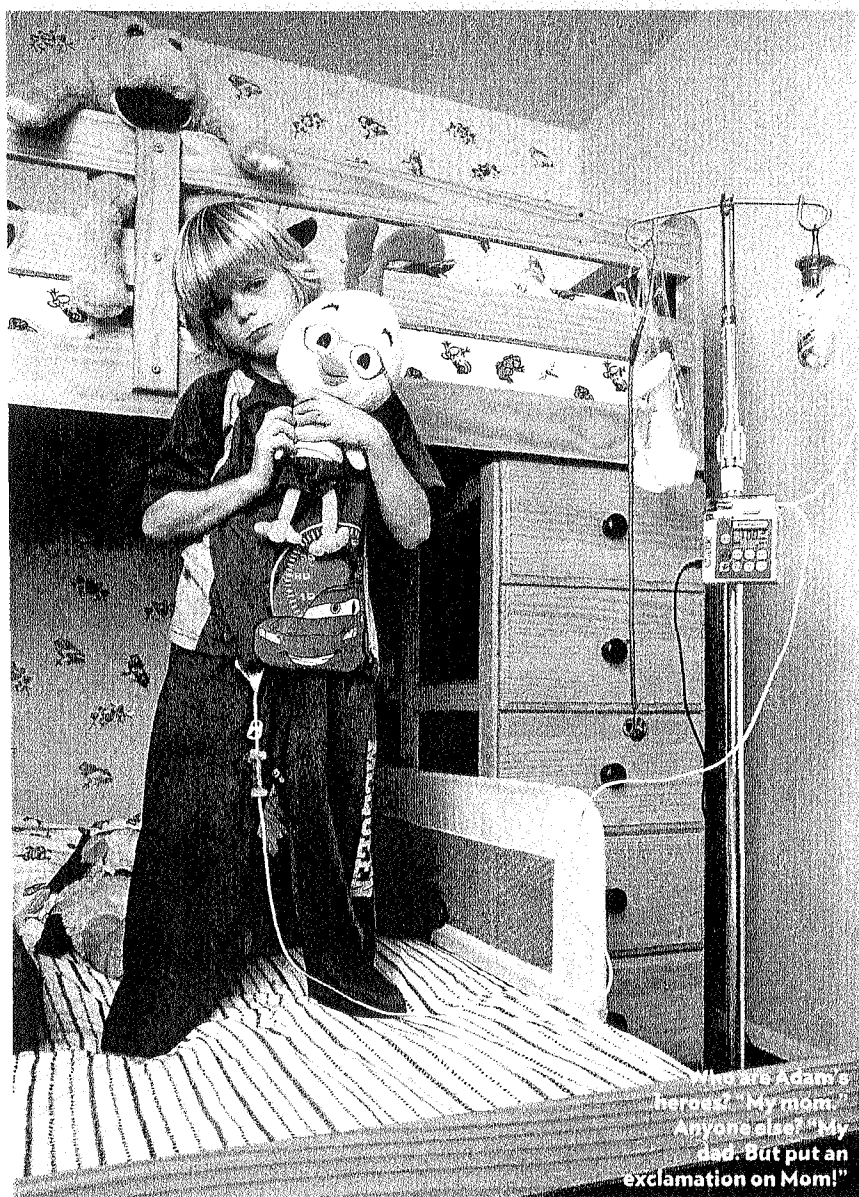
A second-grader at Uwchlan Hills Elementary School in Downingtown, Pa., Adam dispatches his homework, makes friends and commands playground football games with ease. The one thing he can't do: eat. Allergic to almost all food, Adam is hampered by eosinophilic esophagitis (EE), a gastrointestinal disorder that in this extreme form affects roughly 1 in 50,000 people. Far from filling Adam up, food inflames his esophagus like a toxic invader, triggering vomiting, diarrhea, rashes and infections. So every evening around 7 p.m., Adam's mother, Annette, plugs

a tube into a small surgically created opening above Adam's bellybutton that connects to his stomach. For the next 12 hours, tethered to an IV pole as he sleeps, Adam absorbs an oatmeal-colored, amino acid-based formula that provides the nutrition he needs. "It's annoying," Adam says. "But it's how I stay alive."

Further complicating his young life, Adam also suffers from the gastrointestinal disorder Crohn's disease, asthma and Ilven, a rare skin condition. "His immune system isn't working right in a number of ways," says Dr. Chris Liacouras, Adam's pediatric gastroenterologist at the Children's Hospital of Philadelphia. "He's one of the first we diagnosed [with EE] and he's kind of teaching us." Until he was

5, Adam could take in only ice chips and unflavored snow cones. Over the last two years, month-long food trials have turned up six fruits (apples, bananas, oranges, pears, grapefruits, watermelon) and two vegetables (carrots, green beans) that no longer ravage his esophagus. Liacouras says the list may eventually expand, but Adam's current relationship with food is hardly normal, which may explain why the 46"-tall, 44-lb. dynamo would rather talk about sports, computer games or practically anything else. "Sometimes," says Annette, 42, "I wish food would go away."

Adam seemed a perfectly healthy infant until his sixth month, when Annette had to stop breast-feeding for medical reasons. Within 24 hours



“We are Adam’s heroes,” my mom. “Anyone else?” my dad. But put an exclamation on Mom!”

“Sometimes, I wish food would go away”

—ANNETTE TURNER, ADAM’S MOM

spoon-feed himself ice chips from a cereal bowl. She soon began hating food herself. “I didn’t put anything in my mouth in front of him for about six months,” she says. After dropping 15 lbs., Annette forced herself to eat in front of Adam—which brought new challenges. In mall food courts he’d inhale and say, “Ah, french fries.” At dinner, he’d climb into his mom’s lap to touch and smell—but not eat—her food. Adam now says he finds watching people eat “boring.”

If Adam’s diet is severely restricted, his life is anything but. “We’re adrenaline addicts; we love adventure,” Annette says. Since infancy, Adam has logged thousands of miles on bikes and motorcycles, strapped to his dad’s back. He also surfs, plays soccer and baseball and goes on family trips. “We’ve hooked up feeding bags in parking lots and on highways,” Annette says. Adds Mike: “We don’t make a big deal, so he doesn’t.” That low-key approach extends to Adam’s school, where few people, classmates included, are aware of his condition. Sometimes at lunch he strays from his approved diet and experiments with hamburgers and cookies—then pays for it with gastrointestinal discomfort. “You would never know,” says cafeteria manager Beverly Frederick.

Adam prefers it that way. At 7, he just wants to be like other kids. Still, he’s aware of the toll his disability takes on his family. “One day he said, ‘Mom, did you really want a kid that has all these diseases?’” Annette says. “He tries to be tough, but he’s got a big heart.” The limited body of existing EE research indicates a normal life span for Adam, but Annette takes no day for granted. “What I’ve done with Adam in seven years is more than some mothers do in a lifetime,” she says. “I try to squeeze every minute out of every day.”

of starting on formula, Adam began to vomit, had trouble breathing and suffered his first skin eruption. Doctors diagnosed a milk-protein allergy and, to give Adam’s GI tract a rest, inserted a feeding tube that ran from his nose to his stomach. The tube, part of which had to be taped to his face, was clumsy and easily dislodged, and Annette often had to wrestle it back into place. Still, she says, “we thought, No biggie.”

But the worst was yet to come. After being introduced to mashed bananas, rice cereal and other baby foods, Adam began to lose weight, plagued by up to 12 bouts of diarrhea a day. This time, tests revealed EE, which, says Dr. Liacouras, “can be one food or it can be all food.” In Adam’s case, skin-prick testing proved him allergic to all foods, except carrots and — a discovery

that tortured Annette. “To find I’d been basically poisoning him while feeding him...” she says, tearing up. “That was the most painful thing.” Adam was 2½ when his reluctant parents agreed to have a device surgically implanted so that formula could be pumped directly into his stomach.

Adam quickly gained weight, and began to sleep better—a peace that eluded his parents, awakened up to 10 times a night by an alarm that signaled when Adam’s feeding tube was tangled. “It was worse than having a newborn,” recalls Adam’s dad, Mike Rubin, 56. Desperate, Mike, a health-care administrator, and Annette, a corporate controller, leaned on disability insurance to bring in night nurses.

But that did little to ease Annette’s anguish at meals as she watched Adam

HOUSE BILL 1436

Synopsis

- House Bill 1436 requires insurers to provide coverage and reimbursement of amino-acid based elemental formulas when prescribed by a physician for conditions such as severe multiple protein allergies, eosinophilic disorders, GERD, Short Bowel Syndrome.
- Although used to treat such medical conditions, amino acid-based elemental formulas are not universally treated the same way as other medically necessary procedures and pharmaceuticals with respect to coverage and reimbursement.
- Universally, insurers will cover these medical formulas when an infant or child is admitted to a hospital or if they are given the liquid by means of a feeding tube. This indicates insurers understand the medical necessity of these formulas/medical foods.
- Providing the formula through a bottle rather than through hospital admission, and when prescribed by a physician, immediately reduces medical costs.
- It is estimated that one-tenth of one percent (0.1%) or lower of children under five years of age have severe multiple allergies. These formulas are used when all other type formulas have failed so these are the sickest of the sick children. Of the small percentage with severe multiple food allergies, approximately 80% outgrow the need for these formulas within 18-24 months.
- Pennsylvania's public assistance programs (Medicaid and Women, Infants and Children (WIC) programs) provide for this coverage, whereas private insurers generally do not.
- Currently there are 12 other states that require insurers to provide coverage and reimbursement for amino acid-based formulas.

HOUSE BILL 1436

FAST FACTS

- A food allergy is different than a food or soy intolerance. Food intolerance is a digestive system response. It occurs when something irritates a person's digestive system. Common symptoms are nausea, stomach pain, vomiting or diarrhea.
- A food allergy develops when the body's immune system becomes misdirected and attacks harmless food proteins. Food allergies differ from other allergies because even a miniscule amount of the wrong (offending) food can be fatal.
- Common symptoms of food allergy are rash/hives, diarrhea, stomach pain, itchy skin, shortness of breath, chest pain, swelling of the airways to the lungs, or anaphylaxis.
- Approximately 150 people die from food allergies each year and over 30,000 receive lifesaving food allergy treatment in emergency rooms each year.
- 90% of all food allergic reactions are caused by, milk, eggs, shellfish, peanuts, fish, soy, wheat, tree nuts (e.g., walnuts, pecans).
- Cow's milk protein allergy is a condition wherein children are allergic to the proteins that are found in cow's milk, breast milk, soy, wheat, potato chips and many other foods. The incidence of this condition is estimated at less than 1% of the population. Symptoms include difficulty swallowing, abdominal pain, malnutrition, failure to grow, uncontrolled reflux, nausea, vomiting, bloody stools, difficulty sleeping, and diarrhea. Children typically outgrow these allergies within the first 5 years of life.
- Eosinophilic gastrointestinal disorders (EGID's) are relatively new and are estimated to afflict 1 in 10,000 children. Eosinophils are white blood cells that are normally associated with fighting parasitic infections. Rarely, eosinophils respond to food and flood areas of the gastrointestinal tract. Symptoms include difficulty swallowing, abdominal pain, malnutrition, failure to grow, uncontrolled reflux, nausea, vomiting, food impactions where food actually gets stuck in the esophagus, difficulty sleeping, and diarrhea. This disease is often not diagnosed until ages 4 and up. Some children who started as cow milk protein allergic children later develop EGID's.
- There are no medications to cure these disorders - only treatment options.

- Amino acid-based elemental formulas or elemental medical foods contain no whole or partial proteins, which cause allergies and inflammation. They contain only amino-acids. Due to the synthetic stripping out of proteins, these formulas can be expensive to make and purchase.
- Patients with these diseases cannot consume regular foods. Their bodies will not tolerate it. Elemental formula/medical foods are nutritionally complete meaning that with the use of these products, these patients obtain all the required nutrients that are missed since they are not consuming regular foods.
- If a child is admitted to the hospital and given these formulas, or if the formula is given through a feeding tube inserted in a child's stomach, the insurance companies will pay for them. However, if that same child is being treated at home with the formula and can take the formula through a bottle or a cup, most insurance companies will not pay for the formula.