

Policy #: 304

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Title

Special Foods

(Special Infant Formula, Enteral Formula, Ketogenic Diet for Seizures, and Formula Infusion Pumps)

NOTE: All requests for **outpatient retail pharmacy** items for indications listed and not listed on the medical policy guidelines may be submitted to the BCBSMA Clinical Pharmacy Program by completing the **Prior Authorization Form** on the last page of this document. Patients must have pharmacy benefit coverage in their subscriber certificates.

When services are covered

We cover special medical formulae including **low protein food products*** in accordance with Massachusetts State Mandate¹ for the medically necessary treatment of certain inborn errors of metabolism⁵ caused by the following conditions:

- Phenylketonuria (see PKU guidelines³ below)¹⁵
- Tyrosinemia
- Homocystinuria
- Maple syrup urine disease
- Propionic acidemia
- Methylmalonic acidemia
- Urea cycle disorders¹²
- Other organic acidemias¹²
- Food protein enterocolitis.²⁰

Coverage for low protein foods is covered per applicable state mandate and benefit limits.¹

*PKU benefits are provided for infants and children as well as for the protection of unborn babies of women who have PKU.¹

We cover non-prescription enteral formulae^{6,7,8} with a written physician's order in accordance with Massachusetts State Law² for the medically necessary treatment of documented malabsorption caused by the conditions listed below. We also cover non-prescription enteral formulae for the inability to eat food caused by the following conditions:

- Allergic eosinophilic esophagitis²⁰
- Crohn's disease
- Ulcerative colitis
- Gastroesophageal reflux
- Gastrointestinal dysmotility
- Chronic intestinal pseudo-obstruction (Ogilvie's syndrome)

We cover enteral formulae prescribed by a licensed practitioner for infants under 1 year of age.¹⁸

We cover enteral formulae prescribed by a licensed practitioner for use in enteral feeding tubes (N-G tube, N-E feeding tubes, G-tubes, J-tubes) with a written physician's order. Feedings must exceed 750 kilocalories a day (for adult patients) to be considered medically necessary.⁴ Please note there are no kilocalories minimums in pediatric patients. Tube feedings are required under the following circumstances:

- An anatomic or structural problem that prevents food from reaching the stomach, for example a tumor or stricture of the esophagus or stomach, or neck cancer.
- A neurological problem that results in swallowing and chewing problems that may lead to aspiration.

We cover use of an FDA-approved infusion pump to administer the enteral feedings in the following circumstances:

- For patients with dumping syndrome who cannot tolerate bolus feedings *or*
- For use in J-tube (jejunostomy) feedings *or*
- For patients with inflammatory bowel disease who require small amounts of slow, continuous feedings *or*
- For patients who, through surgery or congenital abnormality, do not have a stomach and who require slow, continuous feedings.

We cover ketogenic diet for children with seizures, refractory to or intolerant of multiple anti-epileptic drugs.^{10,16,17,19} The ketogenic diet should be initiated during an **inpatient stay**.¹⁹

PKU Guidelines:³

- Treatment of neonates born with PKU should begin 7-10 days after birth.¹⁴
- All infants with blood phenylalanine levels over 10 mg/dL measured while eating a normal protein diet (2-3 grams protein/kg/day), and in whom other amino acids levels, such as tyrosine, are low or normal.
- The PKU enteral formula should be enriched with tyrosine, and provide 2-3 grams protein/kg/day. It should be taken as evenly as possible throughout the day.
- Blood phenylalanine levels should be monitored weekly¹⁴ during periods of rapid growth, fluctuating blood levels, or when food intake is unpredictable. In older children and adults, this monitoring can occur 1-2 times per month. The ideal time for this blood test is 2 hours after eating.
- Diet, including special formula intake, is modified to achieve optimal blood levels.
- Optimal blood phenylalanine levels:

under age 10	2-6 mg/dL
over age 10	2-10 mg/dL
women trying to conceive ¹⁴	2-6 m/dL
pregnant women ¹⁴	2-6 m/dL
- Women who wish to have children should optimize their levels 2-3 months *before* conception,¹⁴ and continue close nutritional monitoring during pregnancy.

When services are not covered

According to our subscriber certificates, **we do not cover any over-the-counter nutritional items**. However, we do adhere to the Massachusetts State mandate.

- We do not cover **special medical formulas or non-prescription enteral formulae** when used for other conditions not listed above.
- We do not cover **blenderized baby food or regular store-bought food** for use with an enteral feeding system.
- We do not cover use of **over-the-counter foods or prescription foods** when store-bought food meets the nutritional needs of the patient.
- We do not cover food for the ketogenic diet, since this diet uses regularly available foods.

Individual consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. For example, in certain patients with milk soy allergies⁹, anorexia nervosa, and refractory eczema¹³, individual nutrition coverage decisions may be required. For consideration of an individual patient, physicians may send relevant clinical information to:

Blue Cross Blue Shield of Massachusetts
Clinical Pharmacy Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289

* **NOTE:** When a provider is requesting a *renewal* for authorized formula, additional clinical information describing the young child's current nutritional status and plan for the introduction of other foods must be submitted.

Managed care and Indemnity guidelines

For state mandate regarding **special medical formulae**:

- Prior authorization and yearly re-approval are required. However, for PKU, one-time life-long approval may be given, as long as the patient remains under a BCBSMA plan.
- Any specialist visit requires a referral for Medicare HMO Blue.
- For all other Managed Care plans, any specialist visit requires a referral, except for visits performed by OB/GYN specialists.

For state mandate regarding **non-prescription enteral formulae**:

- Prior authorization is required and yearly re-approval may be given.
- Prior authorization can be obtained by the member through customer service.
- Any specialist visit requires a referral, except for visits performed by OB/GYN specialists.

Indemnity and PPO guidelines

All authorization requirements are determined by the individual's subscriber certificate, however:

- Authorizations are required for all inpatient services.
- Authorizations are not required for most outpatient services as determined by the individual's subscriber certificate.
- Referrals to a specialist are not required.

Coding information

Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

HCPCS Level II codes for enteral formula are:

- **B4034**, Enteral feeding supply kit; syringe fed, per day
- **B4035**, Enteral feeding supply kit; pump fed, per day
- **B4036**, Enteral feeding supply kit; gravity fed, per day

- **B4081**, Nasogastric tubing with stylet Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- **B4082**, Nasogastric tubing without stylet
- **B4083**, Stomach tube - Levine type
- **B4087**, Gastrostomy/jejunostomy tube, standard, any material, any type, each
- **B4088**, Gastrostomy/jejunostomy tube, low-profile, any material, any type, each
- **B4102**, Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
- **B4103**, Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
- **B4104**, Additive for enteral formula (e.g., fiber)
- **B4149**, Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- **B4150**, Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- **B4152**, Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- **B4153**, Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- **B4154**, Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- **B4155**, Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit
- **B4157**, Enteral formula, nutritionally complete, for special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- **B4158**, Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
- **B4159**, Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
- **B4160**, Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- **B4161**, Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- **B4162**, Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- If a member has a pharmacy benefit, enteral formulae must be processed through the pharmacy benefit.

- Participating pharmacies under contract with Express Scripts®, Inc. (ESI), bill all outpatient retail drug claims through the on-line system.
- A participating home infusion therapy provider may bill for enteral formulae for members who do not have a pharmacy benefit.

Policy update history

Issued 4/96 in accordance with the Massachusetts state mandate and local Medicare regulations. Revised 2/97 to allow for a life-time authorization for PKU, and to specify number of calories required for medical necessity, and exclusions for store bought food, in accordance with national BCBSA policy. Additional educational material added 7/97. Reviewed 4/98; added individual consideration for home enteral formula coverage for allergic colitis, milk soy allergies and anorexia nervosa. Updated 1/99 to add inpatient coverage for ketogenic diet induction. Reviewed 1/00, no changes in coverage were made. Updated 5/00 to include coverage for infants and children with allergic enteropathy, including allergic colitis. Updated 11/00 to include coverage for urea cycle disorders and other organic acidemias, and to include individual consideration guidelines for refractory eczema. Pediatric formula selection table updated – thanks to Mark Ogino, MD & Jamie Sheldon, RD, Massachusetts General Hospital. Reviewed 5/01, no changes in coverage were made. Reviewed 3/02, no changes in coverage were made. Updated 5/02 (MPG – GI), to remove allergic enteropathy including allergic colitis under the special medical formulae covered indication section, as this condition is not considered inborn errors of metabolism. Reviewed 11/02 (MPG – Pediatrics), no changes in coverage were made. Reviewed 1/03 MPG Neurology, no changes in coverage were made. Reviewed 3/03, MPG Allergy, no changes in coverage were made. Reviewed 11/03 MPG pediatrics, no changes in coverage were made. Updated 1/2004 to include individual consideration guidelines for infants who are intolerant of breast milk or baby formula. Reviewed 1/04 MPG neurology, no changes were made. Reviewed 3/04 MPG Pulmonology, Allergy and ENT/Otolaryngology, no changes in coverage were made. Reviewed 5/04 MPG pediatrics, no changes in coverage were made. Reviewed 11/04 MPG gastroenterology, nutrition, and organ transplants, no changes in coverage were made. Reviewed 1/05 MPG neurology, no changes in coverage were made. Reviewed 3/05 MPG Pulmonology, Allergy and ENT/Otolaryngology, no changes in coverage were made. Updated 4/05 to include the 2004 BCBSA Association’s policy references on ketogenic diet as a treatment of refractory epilepsy. Reviewed 5/05 MPG- Pediatrics, no changes in coverage were made. Updated 11/05 MPG Gastroenterology, Nutrition and Organ Transplants, policy clarified to include the State Mandate statement on Special Medical Formulas under footnote #1 and to clarify that ketogenic diet should be initiated during an inpatient stay of approximately 5 days based upon BCBSA National policy 2.01.32. Reviewed 1/06 MPG- Neurology, no changes in coverage were made. Reviewed 3/06 MPG-Pulmonology, Allergy, ENT/Otolaryngology, no changes in coverage were made. Reviewed 5/06 MPG-Pediatrics, no changes in coverage were made. Reviewed 11/06 MPG-Gastroenterology, Nutrition and Organ Transplants, no changes in coverage were made. Updated 1/07 to include coverage for infants under 1 year of age who are intolerant of breast milk or baby formula. Reviewed 1/07 MPG Neurology, no changes in coverage were made. Reviewed 2/07 MPG- Psychiatry, Ophthalmology and Endocrinology, no changes in coverage were made. Reviewed 3/07 MPG- Pulmonology, Allergy and ENT/Otolaryngology, no changes in coverage were made. Reviewed 5/07 MPG-Pediatrics, no changes in coverage were made. Reviewed 11/07 MPG-Gastroenterology, Nutrition and Organ Transplants, no changes in coverage were made. Reviewed 1/08 MPG-Neurology, no changes in coverage were made. Reviewed 2/08 MPG- Psychiatry, Ophthalmology and Endocrinology, no changes in coverage were made. Reviewed 3/08 MPG- Pulmonology, Allergy and ENT/Otolaryngology, no changes in coverage were made. Reviewed 5/08 MPG-Pediatrics, no changes in coverage were made. 8/08 Based on the decision from the Implementation sub-BAC committee meeting (August 20, 2008) addressing the recent Sate mandate change pertaining to a dollar maximum per year for low protein foods the document was edited to remove the reference to a dollar amount allowed for low protein foods. The sub-BAC committee clarified that members should refer to their *Benefit Design* language to determine benefit coverage rather than this evidenced based medical policy. Reviewed 11/08 MPG – Gastroenterology, Nutrition & Organ Transplants, no changes in coverage were made. Reviewed 1/09 MPG – Neurology and Neurosurgery, no changes in coverage were made. Reviewed 2/09 MPG – Psychiatry, Ophthalmology and Endocrinology, no changes in coverage were made. Reviewed 3/09 MPG – Pulmonology, Allergy/Asthma/Immunology and ENT/Otolaryngology, no

changes in coverage were made. Updated 5/09 to include the narrative of all enteral formula codes and update of diagnoses: food protein enterocolitis and allergic eosinophilic esophagitis as requested by local experts at the MPG meeting. Reviewed 5/09 MPG-Pediatrics, no changes in coverage were made. Reviewed 11/2009 MPG – Gastroenterology, Nutrition and Organ Transplantation, no changes in coverage were made.

Scientific background, Rationale and References

¹ Chapter 655 of the Acts of 1983, Massachusetts General Laws, HMO Blue with prescription coverage BCBSMA subscriber certificate. The Mandates states that: ...”Coverage shall include those **special formulas** which are approved by the commissioner of the Department of Public Health, prescribed by a physician, and are medically necessary for the treatment of phenylketonuria, tyrosinemia, homocystinuria, maple syrup urine disease, propionic acidemia, or methylmalonic acidemia in infants and children or medically necessary to protect the unborn fetuses of pregnant women with phenylketonuria...”

² Chapter 683 of the Acts of 1987, Massachusetts General Laws

³ Guidelines submitted and approved 3/94 based the following literature:

- Recommendations on the Dietary Management of PKU, *Arch Dis Child*; 68:426-7 1993 (Report of the Medical Research Council Working Party on PKU)
- Effect of Age at Loss of Dietary Control on Intellectual Performance and Behavior of Children with PKU *NEJM*; Vol 314, No. 10, 1986
- Neurological Deterioration in Young Adults with PKU *Lancet*; 336:602-5.

⁴ Based upon a 10/96 National Blue Cross Blue Shield Association policy. Generally, a daily caloric intake of 2000-2200 calories is sufficient to maintain body weight. If fewer than 750 calories are taken daily by enteral nutrition, they are considered supplemental, and are not medically necessary.

⁵ See the American Academy of Pediatrics Committee on Nutrition recommendations *on Reimbursement for Medical Foods for Inborn Errors of Metabolism*, published in *Pediatrics* vol. 93 No. 5 May 1994. Inborn errors of metabolism include phenylketonuria, maple syrup urine disease, homocystinuria, methylmalonic acidemia, propionic acidemia, isovaleric acidemia (and other disorders of leucine metabolism), glutaric acidemia type I, tyrosinemia types I and II, and urea cycle disorders. Treatment might include restriction of specific amino acids, restriction of total nitrogen intake, or supplementation of certain substances. If left untreated, these diseases cause severe mental retardation or death. US Public Law 100-290 defines medical foods 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 principals, are established by medical evaluation.” (1988 Orphan Drug Amendments Act to amend the FDA provisions regarding orphan drugs). Since passage of this act, many states provided funding for such products through Medicaid, and most states offered assistance through the Crippled Children’s and Women, Infants, and Children’s (WIC) programs.

⁶ See the American Academy of Pediatrics Committee on Nutrition recommendations *on Soy-Protein Formulas: Recommendations for Use in Infant Feeding*, published in *Pediatrics*, vol. 72 No. 3 September 1983. The use of soy formula for the following clinical indications is discussed:

Lactose Intolerance and Galactosemia: Soy protein formulae are lactose-free, thus soy-protein formula is the feeding of choice. Any secondary lactose intolerance resulting from enteric infection or other causes of mucosal damage can be managed with soy formula. After diarrhea and intestinal damage is resolved (secondary lactose intolerance), resumption of cow’s milk protein is appropriate, generally 2 weeks after cessation of diarrhea.

Prematurity: These formula should not be used for prolonged feeding of very low birth weight infants, due to poorly understood effects on calcium and phosphate metabolism. However, they should be used for specific therapeutics indications, and for periods not longer than 3-4 weeks.

Management of Cow's Milk Allergy: Soy formula has long been recommended for cow's milk allergy. However, because cow's milk allergy frequently leads to small bowel damage, including villous atrophy, mucosal permeability to other proteins may result in systemic uptake and immunologic responses to other proteins. Serious gastrointestinal reactions to soy protein include severe vomiting, diarrhea, and weight loss, as well as a flattened intestinal mucosa. This data was documented in a series of 4 infants with colitis and persistent diarrhea, who had documented systemic allergic manifestations to soy protein. Thus, severe cow's milk allergy may result in mucosal changes that result in a broader allergic response to other proteins. Therefore, in infants with clinical manifestations of allergic disease, a less-antigenic formula, such as a hydrolysate, is warranted.

Colic: Colic is a common symptom complex comprising abdominal pain and severe crying, presumably related to some gastrointestinal etiology. Various possible factors have been implicated: overfeeding, allergy, carbohydrate intolerance, and others. However, only rarely does a dietary change result in prevention of further attacks. In most infants, symptoms resolve spontaneously by 4 months of age. One study comparing cow's milk formula, soy formula, and a protein hydrolysate, found that symptoms were unrelated to diet in 39% of infants. 18% were without symptoms while receiving soy, and more than half (53%) were unchanged, or colic was worse while receiving soy or cow's milk-protein formula, yet symptoms resolved when casein hydrolysate was given. Any conclusions are tentative at this time, and controlled studies are needed.

Summary:

Soy formula should be considered in the following circumstances:

- vegetarian families who wish to avoid animal proteins
- galactosemia, primary lactase deficiency
- the recovery phase of secondary lactose intolerance
- potentially allergic infants (with a family history of atopy) who have not shown clinical manifestations of allergy (these infants should be monitored for soy allergy)

Soy formula should **NOT** be used in the following circumstances:

- routine feeding of premature and low birth-weight infants (duration of use should be limited, if used at all)
- dietary management of documented clinical allergic reactions to cow's milk protein and or soy protein formula
- routine management of colic

⁷ See the American Academy of Pediatrics Committee on Nutrition recommendations on *Hypoallergenic Infant Formulas*, published in *Pediatrics*, vol. 83 No. 6, June 1989. Antigenic components of human milk and other feedings may cause adverse reactions in some infants with milk-protein intolerance. Reactions include those associated with atopy: angioedema, urticaria, wheezing, vomiting, and eczema. Other findings have also been associated with cow and soy milk ingestion: pulmonary hemosiderosis, malabsorption with villous atrophy, and eosinophilic enterocolitis. Colic, sleeplessness, and irritability, on the other hand, are common symptoms seen in almost all infants at some time, including infants with immune-mediated reactions to dietary antigens. Determining whether adverse reactions are immune-mediated is challenging. Double-blind antigen challenge may be useful, but is sometimes difficult to interpret when appearance of symptoms may be delayed beyond several hours. In vitro testing is compromised by competing forms of immunoreactivity, found in a large percentage of infants who are not symptomatic. Lack of standardization of these T cell-mediated tests is also problematic. Efforts to protect against development of immune-mediated reactions to dietary antigens in high-risk infants, and efforts to eliminate repeated reactions in infants with documented hypersensitivity include the following:

- promote human milk feeding, while delaying introduction of solid foods until beyond 6 months of age

- using different protein sources, such as soy or goat’s milk protein
- altering the antigenicity of cow’s milk protein through chemical alteration of native protein antigens

Casein hydrolysate, digested in vitro using enzymatic hydrolysis, has long been used for infants with defects in protein digestion and adverse reactions to intact cow’s milk protein. More recent formulae with heat-treated and hydrolyzed whey proteins have been introduced. No published, well-controlled double-blind studies exist to support the use of either casein or whey hydrolysates for the prophylaxis or treatment of infants with milk hypersensitivity. Casein hydrolysate formulae, have been extensively used, nonetheless, to treat infants with immune-mediated reactions to cow’s milk. Treatment failures are rare.

Summary: Development of atopic and other immune-mediated reactions to dietary antigens is not completely understood. The amount of antigen, age at introduction, and antigen nature (egg, milk, wheat, etc), maternal immunity, integrity of the mucosal barrier, and heredity all play a role in determining immune responses to dietary antigens. Human milk and casein or whey hydrolysates may be useful in the prophylaxis or elimination of symptoms in sensitized infants. Hydrolysates of < 1,2000 molecular weight have a theoretical advantage over other hydrolysates. There is no evidence to support the use of hydrolysate formulae for the treatment of colic, sleeplessness, or irritability. These common symptoms occur frequently in infants, but rarely as a result of immune-mediated reaction to cow’s milk protein.

PEDIATRIC FORMULA SELECTION TABLE

⁸ Adapted from *An Algorithm for Pediatric Enteral Alimentation* by Wilson SE, Dietz, WH, Grand, RJ, *Pediatr Ann* 1987 16:233, thanks to Boston’s Childrens Hospital, 1996. Updated 12/00- thanks to Mark Ogino, MD & Jamie Sheldon RD, Massachusetts General Hospital, Boston.

CONDITION	NEEDS	FORMULAE
Healthy Term Infant	Intact Protein Milk-Based	Breast Milk Enfamil with Iron Similac with Iron Carnation Good Start
< 34 weeks gestation	High Protein & Minerals MCT Oil	Enfamil Premature Similac Special Care
Primary or Secondary Lactose Intolerance	Lactose Free	Lactofree Prosobee Isomil Carnation Alsoy
Protein Sensitivity	Soy Protein	Prosobee Isomil Carnation Alsoy
Sensitive to Soy and Casein:	Casein Hydrolysate	Nutramigen Pregestimil Alimentum
	Free Amino Acids	Neocate*
Renal Dysfunction	Low RSL Electrolytes	Similac PM 60/40
Steatorrhea, Lymphatic Dysfunction, Pancreatic Enzyme or Bile Acid Deficiency	MCT Oil	Pregestimil (55% MCT) Alimentum (50% MCT) Portagen (86% MCT)
Severely Abnormal Nutrient Absorption (“Short Gut”) or Severe Protein Calorie Malnutrition	Casein Hydrolysate MCT Lactose & Sucrose Free	Pregestimil
Inborn Errors of Metabolism	Nutrient-Specific Formulae	(According to Diagnosis)
Carbohydrate Intolerance	Low CHO or CHO-Free	3232A

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* Orphan over-the-counter drug; does not require a prescription, but should be used under the supervision of a physician

Comparison of Milk-Based Infant Formulae

Product	Cal	Protein	CHO	Fat	Osm	Fe	\$*
Breast Milk	.67/cc	6% 10.5 gm/L human milk (whey dominant)	42% 72 gm/L lactose	52% 39 gm/L	290	0.3 mg/L	-
Enfamil w/Fe 20 (Mead Johnson)	.67/cc	8% 14.2 gm/L reduced minerals whey & nonfat milk (60:40)	44% 73.7 gm/L lactose	48% 35.8 gm/L palm olein, soy, coconut & high oleic sunflower oils	300	12.2 mg/L	3.40/qt
Enfamil AR	.67/cc	10% 16.7 gm/L reduced mineral whey, non-fat milk	44% 73.3 gm/L lactose (57%), pregelatinized rice cereal (30%), maltodextrin	46% 34 gm/L corn, soy and coconut oils	300	12.2 mg/L	
Similac w/Fe 20 (Ross)	.67/cc	9% 14.5 gm/L nonfat milk	43% 72.3 gm/L lactose	48% 36.5 gm/L soy & coconut oils	300	12.2 mg/L	3.16/qt
Enfamil w/Fe 24 (Mead Johnson)	.67/cc	9% 17.8 gm/L reduced minerals whey & nonfat milk (60:40)	41% 83.4 gm/L lactose	50% 345.5 gm/L palm olein, soy, coconut & high oleic sunflower oils	360	15.2 mg/L	N/A
Similac w/Fe 24 (Ross)	.80/cc	11% 22 gm/L nonfat milk	42% 85.3 gm/L lactose	47% 42.8 gm/L soy & coconut oils	380	14.6 mg/L	N/A
Similac PM 60/40 20 (Ross)	.67/cc	9% 15.8 gm/L whey protein concentrate & sodium caseinate	41% 69 gm/L lactose	50% 37.8 gm/L corn, coconut & soy oils	280	0 mg/L	9.27/qt
Carnation Good Start	.67/cc	10% 16.2 gm/L reduced minerals whey hydrolysate	44% 74.4 gm/L 70% lactose, 30% malto- dextrin	46% 34.5 gm/L palm olein, soy, coconut & high oleic safflower oils	-	10.1 mg/L	2.82/qt

* Costs may vary depending on location and route of purchase

Comparison of Formulae for the Premature Infant

Product	Cal	Protein	CHO	Fat	Osm	Fe	\$*
Enfamil	.8/cc	12%	44%	44%	310	1.8 mg	-

Premature 24 (Mead Johnson)		3 gm/100kcal nonfat milk & demineralized whey	11 gm/100kcal corn syrup solids & lactose	5.1 gm/100kcal MCT oil (40% as MCT), soy & coconut oils		/100kcal	
Similac Special Care 24 w/Fe (Ross)	.8/cc	11% 2.7 gm/100kcal nonfat milk & whey protein concentrate	42% 10.6 gm/100kcal hydrolyzed corn starch & lactose	47% 5.43 gm/100kcal MCT oil, soy & coconut oils	280	1.8 mg /100kcal	-
EnfaCare (Mead Johnson)	.73/cc	11% 2.8 gm/100kcal whey protein concentrate, non-fat milk	43% 10.7 gm/100kcal corn syrup solids, lactose	48% 5.3 gm/100kcal high oleic sunflower oil, soy oil, MCT oil, coconut oil	260	1.8 mg/100kcal	
Neosure (Ross)	.73/cc	10% 2.6 gm/100kcal nonfat milk & whey protein concentrate	41% 10.3 gm/100kcal lactose, glucose polymers	49% 5.5 gm/100kcal soy (51%), high oleic safflower, MCT & coconut oils	290	1.8 mg /100kcal	4.06/qt
Enfamil Human Milk Fortifier (Mead Johnson)*	3.5/ packet	31% 0.28 gm/ packet whey protein concentrate & sodium caseinate	31% 0.28 gm/ packet MCT oil, soy & coconut oils	42% 0.16 gm /packet from caseinate	63 (+BM)	.36 mg/ packet	0.80/ packet
Similac Human Milk Fortifier (Ross)	3.5/ packet	29% 0.25 gm/packet whey protein concentrate, non-fat dry milk	51% 0.45 gm/ packet corn syrup solids	26% 0.1 gm/packet 0.2 MCT oil	90 (+BM)	.09 mg/ packet	

* Costs may vary depending on location and route of purchase

** Per packet

Comparison of Lactose-Free Milk and Soy Protein-Based Formulae

Product	Cal	Protein	CHO	Fat	Osm	Fe	\$*
Lactofree (Mead Johnson)	.67/cc	9% 14.9 gm/L milk protein isolate	42% 70.3 gm/L corn syrup	49% 37.2 gm/L palm olein, soy, coconut & high oleic sunflower oils	200	12.2 mg/L	3.19/qt
Isomil (Ross)	.67/cc	10% 16.6 gm/L soy protein, L-methionine	41% 69.6 gm/L corn syrup & sucrose	49% 36.9 gm/L high oleic safflower oil, soy & coconut oils	230	12.2 mg/L	3.24/qt
Prosobee (Mead Johnson)	.67/cc	12% 20.3 gm/L	40% 67.6 gm/L	48% 35.8 gm/L	200	12.2 mg/L	3.36/qt

Johnson)		soy protein, L-methionine	corn syrup	palm olein, soy, coconut & high oleic sunflower oils			
Carnation Alsoy (Nestle)	.67cc	11% 19 gm/L soy protein isolate, L- methionine	44% 75 gm/L corn maltodextrin, sucrose	45% 34 gm/L palm olein, soy, coconut & high oleic safflower oil	296	12 mg/L	
RCF (Ross)	.67/cc	12% 20 gm/L soy protein, L-methionine	40% 68.3 gm/L (depends upon CHO)	48% 36 gm/L soy & coconut oils	varies based on CHO	15 mg/L	3.28/qt

* Costs may vary depending on location and route of purchase

Comparison of Elemental and Semi-Elemental Infant Formulae

Product	Cal	Protein	CHO	Fat	Osm	Fe	\$*
Nutra- migen (Mead Johnson)	.67/cc	11% 18.9 gm/L casein hydrolysate, L-cystine, L-tyrosine, L-tryptophan	44% 74.4 gm/L corn syrup, modified corn starch	45% 33.8 gm/L palm olein, soy, coconut & high oleic sunflower oils	320	12.2 mg/L	18- 21.59/can 5.50-6.17/qt
Alimentum (Ross)	.67/cc	11% 18.6 gm/L casein hydrolysate, L-cystine, L-tyrosine, L-tryptophan	41% 68.9 gm/L sucrose & modified tapioca starch	48% 37.5 gm/L MCT oil (50% of fat), safflower & soy oils	370	12.2 mg/L	5.59/qt
Pregest-imil (Mead Johnson)	.67/cc	11% 18.9 gm/L casein hydrolysate, L-cystine, L-tyrosine, L-tryptophan	41% 69.6 gm/L corn syrup, modified corn starch & dextrose	48% 37.9 gm/L MCT oil (55% of fat), corn, soy, and high oleic safflower oils	320	12.7 mg/L	21.59/can 6.17/qt
Neocate (SHS)	.67/cc	13% 23.6 gm/L free amino acids	42% 70.9 gm/L corn syrup	36% 27.4 gm/L safflower oil, coconut (50% of fat as MCT), soy oils	342	11.9 mg/L	13.90/qt

3232A (Mead Johnson)	.67/cc (with CHO)	11% 18.8 gm/L casein hydrolysate	51% 89.8 gm/L 37% modified tapioca starch (+ added CHO)	38% 28 gm/L 28% MCT oil, 5% corn oil	360- 640 varies based on CHO	12.5 mg/L	48.50/can (+ CHO)
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* Costs may vary depending on location and route of purchase

Comparison of Elemental and Semi-Elemental Formulae for Children Ages 1-10

Product	Cal	Protein	CHO	Fat	Osm	Fe	\$*
Peptamen Junior (Clintec)	1/cc	12% 30 gm/L casein hydrolyzed whey	55% 137.5 gm/L maltodextrin, sucrose, corn starch	33% 38.5 gm/L MCT oil (60% of fat), soy, canola, lecithin	260	14 mg/L	19.40- 32.50/qt
Pediatric Vivonex (Sandoz)	.8/cc	12% 24 gm/L free amino acids	65% 130 gm/L maltodextrin, modified starch	27% 23.5 gm/L MCT oil (68% of fat), soy oil	360 (unfla- vored)	10 mg/L	23.00/qt (28.75/qt kcal equivalent)
Neocate 1+ (SHS)	1/cc	10% 30 gm/L free amino acids	58% 146 gm/L corn syrup solids	32% 35 gm/L safflower, coconut, canola, MCT	610 (unflavored) 727 (flavored)	7.70 mg/L	14.80/qt

* Costs may vary depending on location and route of purchase

Comparison of Toddler Formulae

Product	Cal	Protein	CHO	Fat	Osm	Fe	\$*
Whole Milk	.63/cc	21% 34.5 gm/L cow's milk	30% 48.4 gm/L lactose	49% 34.5 gm/L butterfat	285	0.5 mg/L	0.84/qt
Carnation Follow-Up	.67/cc	11% 18 gm/L cow's milk, casein predomi nant	52% 89 gm/L corn syrup solids, lactose	37% 28 gm/L palm olein, soy, coconut, high oleic safflower oils	326	12.6 mg/L	2.82/qt
Toddler's Best (Ross)	.67/cc	14% 23.7 gm/L nonfat milk	44% 74.4 gm/L sucrose & lactose	42% 31.8 gm/L high oleic safflower, coconut & soy oils	357	12.2 mg/L	2.92/qt
Next Step (Mead)	.67/cc	10% 17.5 gm/L	44% 75 gm/L	45% 34 gm/L	-	11.5 mg/L	3.19/qt

Johnson)		nonfat milk	corn syrup solids, lactose	palm oleic, soy, coconut, high oleic safflower oils			
Next Step Soy (Mead Johnson)	.67/cc	13% 21 gm/L soy protein isolate	47% 75.5 gm/L corn syrup solids, sucrose	40% 28.2 gm/L palm oleic, soy, coconut, high oleic sunflower oils	-	11.5 mg/L	2.94/qt

* Costs may vary depending on location and route of purchase

Comparison of Intact Protein, Fat-Modified Formulae

Product	Cal	Protein	CHO	Fat	Osm	Fe	\$*
Portagen (Mead Johnson)	.67/cc	14% 24 gm/L sodium caseinate	46% 78 gm/L corn syrup solids, sucrose	40% 32 gm/L MCT oil (34% of total kcals, 86% fat), corn oil (3.5% kcals as linoleic acid)	230	12 mg/L	7.50/qt
Lipsorb (Mead Johnson)	1/cc	14% 42 gm/L sodium caseinate	46% 119 gm/L corn syrup & sucrose	40% 42 gm/L MCT oil (34% of total kcals, 86% fat), corn oil	467	9.3 mg/L	7.50/qt

* Costs may vary depending on location and route of purchase

Comparison of Milk Protein-Based Formulae for Children Ages 1-10

Product	Cal	Protein	CHO	Fat	Osm	Fe	\$*
Pediasure (Ross) **	1/cc	12% 30 gm/L sodium caseinate, whey protein	44% 110 gm/L hydrolyzed corn starch, sucrose	44% 50 gm/L 50% high oleic safflower, 30% soy oil, 20% MCT	365	14 mg/L	1.99/can 7.96/qt
Kindercal (Mead Johnson) ***	1.06 /cc	13% 34 gm/L calcium & sodium caseinate, milk protein	50% 135 gm/L malto-dextrin, sucrose	37% 44 gm/L 50% canola, 15% high oleic safflower oil, 15% corn oil, 30% MCT oil	310	10.6 mg/L	75.20/qt
Resource Just for Kids (Sandoz)	1/cc	12% 30 gm/L sodium & calcium caseinate, whey protein	44% 110 gm/L hydrolyzed corn starch, sucrose	44% 50 gm/L 42% high oleic sunflower oil, 38% soybean oil, 20% MCT oil	390	14 mg/L	5.32/qt
Nutren Junior (Clintec)	1/cc	12% 30 gm/L casein & whey proteins	44% 127.5 gm/L malto-dextrin, sucrose	44% 42 gm/L soybean oil, MCT oil, canola oil	350	14 mg/L	5.34/qt

* Costs may vary depending on location and route of purchase

** available with fiber: 5.1 gm/L (soy)

*** standard with fiber 6.3 gm/L (soy)

⁹ See the *Pediatric Nutrition Handbook, Fourth Edition*, by the American Academy of Pediatrics, Ronald Kleinman, MD, Editor.

Milk Allergy: The handbook states that cow's milk hypersensitivity develops in 2.2-2.8% of infants, yet many of these children will develop tolerance by their third birthday. Authors state that skin prick tests at 1 year of age are valuable predictors of the outcome of mild sensitivity, and the likelihood of other food sensitivities as well. The handbook notes that soy formulae are not less allergenic than are cow's milk formula- diarrhea, vomiting, failure to thrive, colitis, GI bleeding, and colic, skin & respiratory symptoms may occur. Authors state that there is evidence that milk-induced enteropathy (and enteropathies from other foods) are caused by immunologic mechanisms, hence fit the definition of food allergy. However, many infants who vomit, spit up, or have colicky symptoms do not fit this definition. Authors conclude that for infants intolerant of both soy and cow's milk, consideration should be given to other formula, which either contain calcium, or are supplemented by calcium.

Therapy for Various Food Allergies: The handbook notes that clinically significant food hypersensitivity may be far less common than initially thought; relatively few foods are responsible for confirmable allergies. They caution that elimination of staples like milk, eggs, and wheat should be done only when clearly justified by proper diagnostics. Those with milk or soy intolerance should be fed a substitute formula until age 1 or older. The authors recommend that a rechallenge with milk or soy should be undertaken in a controlled setting (IV, epi, O₂ available). Authors suggested that appropriate dietetic counseling is required to design elimination diets. The handbook states that exclusion of a food for 2-4 weeks serves to evaluate any contribution of that food to symptoms. Authors noted that for IgE-mediated reactions, 44% of children under 3 years will likely outgrow the clinical response within 1 to 7 years. For those children in whom sensitivity develops after age 3, authors note that the tendency is not to outgrow the response. Authors note that while many children outgrow the clinical sensitivity, the immediate skin test response remains positive.

Prevention: Before birth of infants who may be at risk for food allergies, authors recommend that maternal diet during pregnancy be unrestricted, they encouraged women to exclusively breast feed for the first 4-6 months (or use a hypoallergenic formula if breast feeding is not possible or supplementation is required). [During lactation] Mothers should eliminate peanut and tree nuts from their diet, and consider eliminating eggs and milk. Authors further recommend that solid food introduction be delayed until after 4-6 months; and cow's milk be delayed until 1 year of age; eggs delayed until 2 years; and peanuts, nuts, and fish delayed until 3 years of age.

¹⁰ Based on the 10/98 TEC (Technology Evaluation Center) assessment of ketogenic diets for children with refractory epilepsy. This analysis evaluated medical literature through 9/98 to examine the question of whether a ketogenic diet results in a clinically significant reduction in seizure frequency for children who were refractory to anti-epileptic drugs (AEDs). Evidence was in the form of uncontrolled, largely retrospective studies. The definition of "refractory to AEDs" varied between studies; however, in general patients had failed or were intolerant to multiple drug regimens. Subjects in some studies had a high mean frequency of seizures (for example, 7-13 per day) and a history of extensive prior trials of medications (up to 6-7 different drugs, in some studies). Most studies required an inpatient admission to initiate the diet, to induce a fast, ensure adequate hydration, nutrition, and to educate the patient and family.

Efficacy: These data are from uncontrolled studies, so spontaneous remission and placebo effect may influence results. However, the magnitude of improvement was considered to be higher than what would be expected from placebo. Spontaneous remission, estimated from one retrospective study, is estimated to be 1.5-4% in a group of children with an even lower frequency of seizures.

% reduction in seizures	% children	95% CI
Complete cessation of seizures	16%	11-22
Over 90% reduction of seizures	32%	25-40
Over 50% reduction of seizures	56%	41-70

Adverse effects: Mild GI symptoms were common, occurring in 1/3 to 1/2 of children in some studies. Nephrolithiasis or metabolic abnormalities occurred in 5% of les of children in some studies. Other reported complications included lethargy, acidosis, constipation, emesis, and increased infections- these effects occurred in 4-8% of children in one study. The effects of this diet on growth and development are not well known; some authors suggested that children may show growth retardation, but this was not systematically examined. As expected, cholesterol and triglyceride levels rise on this diet, and there were reports of cholesterol levels over 250 mg/dL in one study, and a mean of 367 mg/d. The significance of this degree of elevation for 2-3 years at this age is unknown. There is little systematic evidence on patients who have followed this diet for more than a few years.

Adherence: Nonadherence to the diet was high, with up to 45% of patients discontinuing the diet at 12 months in some studies; however, non-adherence was related to efficacy of seizure reduction: for those with over 90% reduction of seizures, about 85% remained on the diet at one year. The overall quality of life on this diet has not been evaluated.

¹¹ Based on recommendations from Ronald Kleinman, MD, Massachusetts General Hospital.

¹² Based on recommendations from Mark Korson, MD New England Medical Center. Conditions include:

Urea cycle disorders including carbamyl phosphate synthetase (CPS) deficiency, ornithine transcarbamylase (OTC) deficiency, citrullinemia (also known as argininosuccinic acid synthetase deficiency), argininosuccinic aciduria (also known as argininosuccinic acidylase deficiency), arginase deficiency.

Organic acidemias including glutaric acidemia, beta-ketothiolase deficiency, isovaleric acidemia, beta-methylcrotonyl CoA carboxylase deficiency.

¹³ Based on recommendations from Eugenia Marcus, MD, President of the Massachusetts Chapter of the American Academy of Pediatrics, MPG 11/00.

¹⁴ Adapted from the National Institute of Health Consensus Statement: *PKU Screening and Management*. Volume 17, number 3, October 16-18, 2000.

Initiation of treatment for infants with PKU: Therapy for infants born with PKU should begin no later than 7-10 days after.

Maternal PKU: Phe levels below 6 mg/dL should be achieved at least 3 months before conception.

¹⁵ Recommendations on Maternal Phenylketonuria from the American Academy of Pediatrics, 2001:

- All girls and women of childbearing age with elevated Phe levels, including those with PKU should be identified and counseled regarding risks of maternal PKU fetal effects with uncontrolled blood Phe levels during pregnancy.
- Women with hyperphenylalaninemia who are unable or unwilling to maintain blood Phe levels should be assisted to obtain adequate means for birth control, including tubal ligation if requested.

- Women with hyperphenylalaninemia who conceive with blood Phe levels greater than 4-6mg/dL should be counseled regarding the risks to the fetus and offered ultrasonography to detect fetal abnormalities.
- Women who give birth to infants with features of maternal PKU fetal effects without a known cause should have blood testing for hyperphenylalaninemia.

¹⁶ Pediatrics volume 108, number 4 October 2001. *The ketogenic Diet: A 3-to 6-year follow-up of 150 children enrolled prospectively.* This study reported that of the 150 patients studied, 13% were seizure-free and 14% had a 90%-99% decrease in their seizures. 29 were free of medications; 28 were on only 1 medication; 15 remained on the diet. The study concluded that ketogenic diet is effective in controlling difficult-to-control seizures in children. As well, it is more effective than anticonvulsants and is well-tolerated.

¹⁷ New England Journal of Medicine, 1998;338:1715-22. *Long-term prognosis of seizures with onset in childhood.* This prospective study reported on 245 children who had active epilepsy. 68 patients had idiopathic seizures, 52 patients had cryptogenic seizures, and 123 patients had remote symptomatic seizures. Follow-up data was available on 220 patients. Of the 220 patients, 176 were alive and 44 had died. 39 patients who died were not seizure-free at the time of death; 33 had remote symptomatic seizures. 112 surviving patients were seizure-free for at least 5 years; 83 patients were not taking anti-epileptic medications. Summary: The authors concluded that while the majority of patients with childhood epilepsy were free of seizures by the time they become adults, they are increased risk for social and educational problems. Also, patients whose epilepsy that do not remit have an increased risk of death.

¹⁸ Recommendations from the MFPC, based on Clinical Pharmacy individual consideration guidelines; January 2004.

¹⁹ Ketogenic Diet as a Treatment of Refractory Epilepsy: Based upon the 2004 Blue Cross Blue Shield Association's national policy 2.01.32. A literature search was performed for the period of 1998 through November 2004 with a focus on outpatient initiation of therapy. At the time of the TEC assessment, there were no studies that examined the safety and efficacy of initiating the diet in an outpatient setting. However, in 2004, Vaisleib and colleagues reported on a case series of 37 patients who underwent outpatient induction of the ketogenic diet, whose outcomes were compared retrospectively to those who underwent inpatient dietary induction. (2) The mean age of the patients was 6.6 years, with a range of 1.8 to 14 years. The authors reported that there was no evidence that inpatient initiation of the ketogenic diet was superior to outpatient initiation. Additional studies identified in the literature search focused on the long-term effects of the ketogenic diet on the growth and development of children (3-5), and whether or not the less restrictive Atkins diet, which also produces a mild ketosis, is option to the ketogenic diet. (6)

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²⁰ Recommendations from local physician experts, March 2009 Medical Policy Group meeting.

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