



I. Insurance Coverage:

Insurance coverage will depend upon your plan, as well as the state you live in. Some states have enacted legislation, which require that reimbursement be provided based on the patient's diagnosis. Below is the information you will need from the product manufacturer (Nutricia North America), your child's physician and your insurance company.

What do I need from the manufacturer?

- Product brochure with detailed description of product including indications (Appendix A below), nutrient information (Appendix B below) and ingredients (Appendix C below)
- Definition of a medical food classification by the Food and Drug Administration (Appendix D below)
- Reimbursement Code/HCPCS Code for specified product (Appendix E below)
- Copy of Invoice/receipt from purchase

What do I need from my child's physician?

- Copies of the patient's medical records including the following
- Patient's medical history
- Diagnosis with ICD 9 Codes (Appendix F below)
- Prognosis (what are the repercussions of not using such a formula?)
- Current nutritional status
- Estimated length of time the patient may require products (it may help if the physician agrees to re-evaluate every 6 months)
- Copy of the prescription written by the pediatrician
- Letter of medical necessity written with physician signatures

What do I need from my insurance company?

- Instructions on methods for filing a formal appeal if denied coverage
- Ask if they have case managers which will handle your case from start to finish
- Make sure you have a copy of your policy coverage (you may need to ask your employer for this information).

What if my claim is denied?

- Utilize all the appeal levels, 1st, 2nd, 3rd and grievance. Write down every person that you have spoken to and what they have said on each date
- Find out if your state mandates coverage and if so, appeal to the state Insurance Commissioner

Appendix A: Indications

Neocate Junior and E028 Splash

- Gastrointestinal tract impairment
- Malabsorption
- Cow and soy milk allergy
- Multiple food protein intolerance
- Eosinophilic esophagitis (EE)
- Short bowel syndrome (SBS)
- Gastroesophageal reflux disease (GERD)
- Other medical conditions for which an amino acid-based diet is required

Appendix B: Nutrient information

Nutrients Per 100 kcal	Neocate Junior Unflavored	Neocate Junior Tropical and Chocolate	E028 Splash
Calories	100	100	100
Protein Equivalent, g	3.3	3.5	2.5
Fat, g	5	4.7	3
Carbohydrate, g	10.4	11	3.5
Linoleic Acid, mg	549	510	264
Vitamins			
Vitamin A, IU (mcg RE)	250 (75)	265 (79.6)	117 (35)
Vitamin D3, IU (mcg)	43.5 (1.1)	46.1 (1.2)	31 (0.78)
Vitamin E, IU (mg a TE)	1.7 (1.1)	1.8 (1.2)	0.82 (0.55)
Vitamin K, mcg	4	4.3	1.5
Thiamine, mg	0.1	0.11	0.055
Riboflavin, mg	0.1	0.11	0.065
Vitamin B ₆ , mg	0.1	0.11	0.08
Vitamin B ₁₂ , mcg	0.19	0.2	0.07
Niacin, mg	0.9	0.95	0.9
Folic Acid, mcg	29.9	31.7	6
Pantothenic Acid, mg	0.4	0.42	0.240
Biotin, mcg	2	2.1	2
Vitamin C, mg	9.3	9.9	3.1
Choline, mg	29.9	31.7	18.3
Inositol, mg	22	23.3	1.8
Minerals			
Calcium, mg	113	120	62
Phosphorus, mg	69.7	73.8	62
Magnesium, mg	16	17	9
Iron, mg	1.5	1.6	0.77
Zinc, mg	0.98	1	0.77
Manganese, mg	0.13	0.14	0.100
Copper, mcg	111	118	100
Iodine, mcg	178	18.9	6
Molybdenum, mcg	4.5	4.8	3.5
Chromium, mcg	3.8	4	3
Selenium, mcg	3	3.2	1.54
Sodium, mg	41	43.5	20
Potassium, mg	137	145	93
Chloride, mg	63	66.7	35

Appendix C: Ingredients

➤ **Neocate Junior:**

Unflavored:

Corn Syrup Solids, Fractionated Coconut Oil, Canola Oil, High Oleic Safflower Oil, L-Arginine, L-Glutamine, L-Lysine-L-Aspartate, Tripotassium Citrate, L-Leucine, L-Phenylalanine, Dicalcium Phosphate, L-Proline, L-Valine, Glycine, L-Isoleucine, N-Acetyl L-Methionine, Tricalcium Phosphate, L-Threonine, Mono and Diglycerides, L-Histidine, L-Serine, Sodium Chloride, L-Alanine, Magnesium Acetate, Choline Bitartrate, L-Tryptophan, L-Tyrosine, Diacetyl Tartaric Acid Esters of Mono and Diglycerides, M-Inositol, L-Ascorbic Acid, L-Cystine, Propylene Glycol Alginate, Taurine, Ferrous Sulfate, L-Carnitine, Zinc Sulfate, DL-Alpha Tocopherol Acetate, Niacinamide, Calcium-D-Pantothenate, Manganese Sulfate, Cupric Sulfate, Thiamine Chloride Hydrochloride, Pyridoxine Hydrochloride, Riboflavin, Vitamin A Acetate, Folic Acid, Potassium Iodide, Chromium Chloride, Sodium Molybdate, Sodium Selenite, Phylloquinone, D-Biotin, Vitamin D3, Cyanocobalamin.

Tropical Fruit:

Corn Syrup Solids, Fractionated Coconut Oil, Canola Oil, High Oleic Safflower Oil, Artificial Flavors, Citric Acid, L-Arginine, L-Glutamine, L-Lysine-L-Aspartate, Tripotassium Citrate, L-Leucine, L-Phenylalanine, Dicalcium Phosphate, L-Proline, L-Valine, Glycine, L-Isoleucine, N-Acetyl L-Methionine, Tricalcium Phosphate, L-Threonine, Mono and Diglycerides, L-Histidine, L-Serine, Sodium Chloride, L-Alanine, Magnesium Acetate, Choline Bitartrate, L-Tryptophan, L-Tyrosine, Diacetyl Tartaric Acid Esters of Mono and Diglycerides, M-Inositol, L-Ascorbic Acid, Artificial Sweetener: Acesulfame Potassium, L-Cystine, Propylene Glycol Alginate, Taurine, Ferrous Sulfate, L-Carnitine, Zinc Sulfate, DL-Alpha Tocopherol Acetate, Niacinamide, Calcium-D-Pantothenate, Manganese Sulfate, Cupric Sulfate, Thiamine Chloride Hydrochloride, Pyridoxine Hydrochloride, Riboflavin, Vitamin A Acetate, Folic Acid, Potassium Iodide, Chromium Chloride, Sodium Molybdate, Sodium Selenite, Phylloquinone, D-Biotin, Vitamin D3, Cyanocobalamin.

Chocolate:

Corn Syrup Solids, Fractionated Coconut Oil, Artificial Flavors, Canola Oil, High Oleic Safflower Oil, Sucrose, L-Arginine, L-Glutamine, L-Lysine-L-Aspartate, Tripotassium Citrate, L-Leucine, L-Phenylalanine, Dicalcium Phosphate, L-Proline, L-Valine, Glycine, L-Isoleucine, N-Acetyl L-Methionine, Tricalcium Phosphate, L-Threonine, L-Histidine, L-Serine, Mono and Diglycerides, Sodium Chloride, L-Alanine, Magnesium Acetate, Choline Bitartrate, L-Tryptophan, L-Tyrosine, Diacetyl Tartaric Acid Esters of Mono and Diglycerides, M-Inositol, L-Ascorbic Acid, Artificial Sweetener: Sucralose, L-Cystine, Propylene Glycol Alginate, Taurine, Ferrous Sulfate, L-Carnitine, Zinc Sulfate, DL-Alpha Tocopherol Acetate, Niacinamide, Calcium-D-Pantothenate, Manganese Sulfate, Cupric Sulfate, Thiamine Chloride Hydrochloride, Pyridoxine Hydrochloride, Riboflavin, Vitamin A Acetate, Folic Acid, Potassium Iodide, Chromium Chloride, Sodium Molybdate, Sodium Selenite, Phylloquinone, D-Biotin, Vitamin D3, Cyanocobalamin

➤ **E028 Splash:**

Grape:

Water, Maltodextrin, Sugar, Fractionated Coconut Oil, Canola Oil, High Oleic Sunflower Oil, L-Arginine, L-Lysine L-Aspartate, Microcrystalline Cellulose, Malic Acid, Calcium Glycerophosphate, L-Leucine, L-Phenylalanine, L-Proline, L-Valine, Glycine, L-Isoleucine, Mono and Diglycerides, Diacetyl Tartaric Acid Esters of Mono and Diglycerides, N-Acetyl L-Methionine, L-Threonine, Dipotassium Phosphate, L-Histidine, L-Serine, L-Alanine, Tripotassium Citrate, Artificial Flavor, Fractionated Coconut Oil, Palm Kernel Oil, Magnesium Acetate, L-Tryptophan, Choline Bitartrate, Calcium Chloride, L-Tyrosine, Trisodium Citrate, L-Ascorbic Acid, Sodium Chloride, Artificial Sweetener (Acesulfame K), L-Cystine, Taurine, Ferrous Sulfate, Zinc Sulfate, L-Carnitine, M-Inositol, Chromium Sulfate, Niacinamide, Manganese Sulfate, Cupric Sulfate, Vitamin E Acetate, Calcium D-Pantothenate, Pyridoxine Hydrochloride, Riboflavin, Vitamin A Palmitate, Thiamine Mononitrate, Sodium Molybdate, Potassium Iodide, Folic Acid, Sodium Hydrogen Selenite, D-Biotin, Vitamin D3, Cyanocobalamin, Phylloquinone.

Tropical Fruit:

Water, Maltodextrin, Sugar, Fractionated Coconut Oil, Canola Oil, High Oleic Sunflower Oil, Artificial Flavor, Citric Acid, L-Arginine, L-Lysine L-Aspartate, Microcrystalline Cellulose, Calcium Glycerophosphate, L-Leucine, L-Phenylalanine, L-Proline, L-Valine, Glycine, L-Isoleucine, Mono and Diglycerides, Diacetyl Tartaric Acid Esters of Mono and Diglycerides, N-Acetyl L-Methionine, L-Threonine, Dipotassium Phosphate, L-Histidine, L-Serine, L-Alanine, Tripotassium Citrate, Fractionated Coconut Oil, Palm Kernel Oil, Magnesium Acetate, L-Tryptophan, Choline Bitartrate, Calcium Chloride, L-Tyrosine, Trisodium Citrate, L-Ascorbic Acid, Sodium Chloride, Artificial Sweetener (Acesulfame K), L-Cystine, Taurine, Ferrous Sulfate, Zinc Sulfate, L-Carnitine, M-Inositol, Chromium Sulfate, Niacinamide, Manganese Sulfate, Cupric Sulfate, Vitamin E Acetate, Calcium D-Pantothenate, Pyridoxine Hydrochloride, Riboflavin, Vitamin A Palmitate, Thiamine Mononitrate, Sodium Molybdate, Potassium Iodide, Folic Acid, Sodium Hydrogen Selenite, D-Biotin, Vitamin D3, Cyanocobalamin, Phylloquinone.

Orange-Pineapple:

Water, Maltodextrin, Sugar, Artificial Flavors, Fractionated Coconut Oil, Canola Oil, High Oleic Sunflower Oil, L-Arginine, L-Lysine L-Aspartate, Microcrystalline Cellulose, Citric Acid, Calcium Glycerophosphate, L-Leucine, L-Phenylalanine, L-Proline, L-Valine, Mono and Diglycerides, Diacetyl Tartaric Acid Esters of Mono and Diglycerides, Glycine, L-Isoleucine, N-Acetyl L-Methionine, Dipotassium Phosphate, L-Threonine, L-Histidine, L-Serine, L-Alanine, Malic Acid, Potassium Citrate, Fractionated Coconut Oil, Palm Kernel Oil, L-Tryptophan, Magnesium Acetate, Choline Bitartrate, L-Tyrosine, L-Ascorbic Acid, Calcium Chloride, Sodium Chloride, Sodium Citrate, L-Cystine, Artificial Sweetener: Acesulfame Potassium, Taurine,



Ferrous Sulfate, Zinc Sulfate, L-Carnitine, M-Inositol, Niacinamide, Manganese Sulfate, Cupric Sulfate, Vitamin E Acetate, Artificial Color (Beet Red, Beta Carotene), Calcium D-Pantothenate, Pyridoxine Hydrochloride, Riboflavin, Vitamin A Palmitate, Thiamine Mononitrate, Chromium Sulfate, Potassium Iodide, Sodium Molybdate, Folic Acid, Sodium Hydrogen Selenite, D-Biotin, Phylloquinone, Vitamin D3, Cyanocobalamin.

Appendix D: Definition of a Medical Food

Food and Drug Administration HHS 21 CFR Ch. 1 (4-1-95 Edition) § 101.9

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;
- 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.”

Appendix E: Product Codes

Neocate Junior (Unflavored):

Product code: 11790

Medicare (HCPCS) code: B4161

Reimbursement code (NDC):
49735-0117-9

Neocate Junior (Tropical):

Product code: 12124

Medicare (HCPCS) code: B4161

Reimbursement code (NDC):
49735-0121-24

Neocate Junior (Chocolate):

Product code: 12690

Medicare (HCPCS) code: B4161

Reimbursement code (NDC):
49735-0126-90

E028 Splash (Grape):

Product code: 12670

Medicare (HCPCS) code: B4161

Reimbursement code (NDC):
49735-0126-70

E028 Splash (Tropical Fruit):

Product code: 12666

Medicare (HCPCS) code: B4161

Reimbursement code (NDC):
49735-0126-66

E028 Splash (Orange Pineapple):

Product code: 11050

Medicare (HCPCS) code: B4161

Reimbursement code (NDC):
49735-0110-50



Appendix F: Diagnosis with ICD-9 Codes

Diagnosis	ICD – 9 Code
Ulcerative colitis	556
Other unspecified noninfectious gastroenteritis and colitis	558.9
Bloody stool(s)	578.1
Multiple food protein allergy	558.3
Atopic dermatitis due to food allergy	693.1
Allergic rhinitis due to food allergy	477.1
Gastroesophageal reflux disease	530.81
Malabsorption	271.3
Failure to thrive/underweight	783.22
Eosinophilic esophagitis	530.19
Eosinophilic enteropathy	569.9
Other and Unspecified Noninfectious Gastroenteritis and Colitis	558.9
Allergic gastroenteritis and colitis	558.3
Celiac Disease	579.0
Other specified intestinal malabsorption	579.8
Dermatitis Due to Substance Taken Internally, Unspecified Due to Food	693.1