

## V. Hypoallergenic Formulas

Hydrolyzed formulas are similar to milk based and soy based formulas with changes made to the protein component. They meet the requirements established by the American Academy of Pediatrics, Committee on Nutrition for the minimum level of 29 nutrients and the maximum level of 9 nutrients. The milk protein (whey or casein) is heat treated and broken down enzymatically to create a protein that is easier to digest. These infant formulas were designed for infants who have problems with the digestion of protein or severe allergy problems to protein. In many cases these formulas are provided to infants with feeding problems or enzyme deficiencies, such as cystic fibrosis. **Most of the protein hydrolysate formulas are lactose free due to the use of sucrose, tapioca starch, corn syrup solids or cornstarch.** The fat in these formulas may contain medium-chain triglycerides (MCT), which are also easier to digest and absorb. Due to the changes in the fat component, some of these formulas are also useful for problems with fat malabsorption, short gut syndrome and severe chronic diarrhea.

Elemental (amino acid) formulas are indicated for confirmed diagnoses of: eosinophilic esophagitis, eosinophilic enteropathy, documented anaphylaxis (pending consultation with allergist), or upon consultative recommendation of an allergist or pediatric gastroenterologist.

All hydrolysate and elemental formulas must be prescribed by a licensed health care provider prior to issuance. According to WIC Federal Regulations (7 CFR, Part 246), monthly formula issuance amounts are based on infant age, feeding choice (partially breastfed or fully formula fed) and form of formula (powder, concentrate, ready to feed). Partially breastfed infants needing supplemental formula may receive a maximum of one can of powdered formula in the first 30 days of life, and will have monthly issuance tailored according to individual need throughout the rest of the first year. WIC maximum formula issuance amounts for all age groups, infant feeding choices and forms of formula are included for each item listed.

**All hydrolysate and elemental formulas will be provided by MaineCare to those WIC participants enrolled in that program. If the infant is not enrolled in MaineCare, the Maine CDC WIC Nutrition Program will provide the formula in amounts not to exceed the federal maximum issuance per month. Prescriptions for these formulas must include:**

- **specific formula name**
- **diagnosis, including ICD-9 code**
- **length of time the product is needed**
- **amount of formula prescribed per day**

Health care providers may use the ***Maine CDC WIC Nutrition Program Medical Documentation for WIC Medical Formula or Medical Food/MaineCare Prior Authorization Form for Formula*** form to obtain approval and prior authorization for MaineCare coverage. **This form must be sent to the local WIC office in order for MaineCare to approve coverage of the formula prescribed.**

## Hypoallergenic Formulas—Hydrolysates

Product Name	Description	Packaging	Composition	Indications	Maximum Monthly WIC Issuance Amounts																			
<b>Nutramigen®</b> and <b>Nutramigen®</b> with <b>Enflora™</b> <b>LGG®</b> (Mead Johnson Nutrition)	Nutritionally complete hydrolyzed protein formula for infants.  <b>Lactose Free</b> <b>Gluten Free</b> <b>Sucrose Free</b> <b>Galactose Free</b>  <b>Note:</b> Nutramigen is available in <b>ready to feed</b> only.  Nutramigen with <b>Enflora LGG</b> is available in <b>powder</b> only.	<b>Powder:</b> 12.6 oz. cans, 6 cans/case (use packed level scoops) <b>Can yield = 87 fl. oz. (standard dilution)</b> <b>NDC: 0087-123941</b>  <b>Ready to Feed Liquid:</b> 32 oz. cans, 6 cans/case <b>NDC: 0087-049901</b>  2 oz nursettes, 48 nursettes per case <b>NDC: 0087-143741</b>	<b>CHO:</b> corn syrup solids, modified corn starch <b>PRO:</b> hydrolyzed casein, L-amino acids <b>FAT:</b> palm olein, soy, coconut, high oleic sunflower, M. alpina, and C. cohnii oils, <b>Probiotic:</b> <i>Lactobacillus rhamnosus GG</i> (powder only)  <b>Vitamins, minerals</b> 20 cal./fl. oz. <b>Osmolality</b> =300 mOsm/kg H <sub>2</sub> O (powder), 270 mOsm/kg H <sub>2</sub> O (32 oz RTF), 320 mOsm/kg H <sub>2</sub> O (2 oz RTF)	Formula for infants and children with sensitivity to intact proteins of milk and other foods, infants with galactosemia, or infants with severe or multiple food allergies. If Nutramigen or Nutramigen Enflora LGG is used as a milk substitute for children >12 months, total dietary calcium should be assessed for adequacy.	<b>Non-breastfed infants</b>																			
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## Hypoallergenic Formulas—Hydrolysates

Product Name	Description	Packaging	Composition	Indications	Maximum Monthly WIC Issuance Amounts							
					Children							
<b>Pediasure Peptide 1.5</b> (Abbott Nutrition)	Nutritionally complete peptide-based medical food.  <b>Gluten free.</b> <b>Suitable for lactose intolerance.</b> <b>Kosher.</b> <b>Halal.</b>	<b>Ready to feed:</b> 8 oz bottles, 24 bottles/case (vanilla)  <b>NDC (for single bottle):</b> <b>70074-0566-56</b>	<b>CHO:</b> corn maltodextrin, short-chain fructooligosaccharides <b>PRO:</b> whey protein hydrolysate, hydrolyzed sodium caseinate <b>FAT:</b> interesterified canola oil, MCT  <b>Vitamins, minerals</b> 44.5 cal/oz. <b>Osmolality = 450</b> mOsm/kg H <sub>2</sub> O	For children ≥12 months with malabsorption, maldigestion or other GI conditions who are fluid restricted or have increased caloric requirements.	<b>Children</b>							
					<b>RTF</b> 8 oz.	113 bottles						
<b>Pregestimil®</b> (Mead Johnson Nutrition™)	Nutritionally complete infant formula with easily digested protein, fat and carbohydrate sources. 55% of fat from MCT.  <b>Lactose Free</b> <b>Sucrose Free</b> <b>Gluten Free</b> <b>Galactose Free</b>	<b>Powder:</b> 16 oz. cans, 6 cans/case (use packed level scoops) <b>Can yield = 112 fl. oz. (standard dilution)</b> <b>NDC: 0087-036701</b>  <b>Ready to Feed Liquid:</b> <b>20 cal/ounce:</b> 2 oz. nursettes, 48 nursettes/case <b>NDC: 0087-143341</b>  <b>24 cal/ounce:</b> 2 oz. nursettes, 48 nursettes/case <b>NDC: 0087-143441</b>	<b>CHO:</b> corn syrup solids, modified corn starch, dextrose (powder only), <b>PRO:</b> hydrolyzed casein, L-amino acids <b>FAT:</b> MCT, soy, high oleic safflower or sunflower, M. alpina, and C. cohnii oils; corn oil (powder only)  <b>Vitamins, minerals</b> 20 cal./fl. oz. Osmolality=320 mOsm/kg H <sub>2</sub> O (powder); 290 mOsm/kg H <sub>2</sub> O (20 cal/oz RTU) 340 mOsm/kg H <sub>2</sub> O (24 cal/oz RTU)	For infants with fat malabsorption, or intact protein sensitivity (such as cystic fibrosis, short bowel syndrome, intractable diarrhea, or severe protein-calorie malnutrition). <b>Not recommended for use in very low birth weight infants.</b> If Pregestimil is used as a milk substitute for children >12 months, total dietary calcium should be assessed for adequacy.	<b>Non-breastfed infants</b>							
					<b>0-3 months</b>				<b>4-5 months</b>		<b>6-11 months</b>	
					<b>Powder:</b> 16 oz.	7 cans	8 cans	6 cans				
					<b>RTF (2 oz.)</b>	416 nursettes	448 nursettes	320 nursettes				
					<b>Partially breastfed infants</b>							
					<b>1-3 months</b>				<b>4-5 months</b>		<b>6-11 months</b>	
<b>Powder:</b> 16 oz.	3 cans	4 cans	3 cans									
<b>RTF (2 oz.)</b>	192 nursettes	224 nursettes	160 nursettes									

## Hypoallergenic Formulas—Hydrolysates

Product Name	Description	Packaging	Composition	Indications	Maximum Monthly WIC Issuance Amounts			
					Non-breastfed infants	0-3 months	4-5 months	6-11 months
<b>Similac Expert Care™</b> <b>Alimentum®</b> (Abbott Nutrition)	Nutritionally complete infant formula with hydrolyzed protein and easily digested fat source.  <b>Lactose Free.</b> <b>RTF is also Corn Free.</b>	<u><b>Powder:</b></u> 16 oz. cans, 6 cans/case (use unpacked level scoops); Can yield = 115 fl. oz (mixed to 20 cal/oz.) <b>Can yield = 115 fl. oz. (standard dilution)</b> <b>NDC: 70074-0576-64</b>  <u><b>Ready to Feed Liquid:</b></u> 32 oz. bottles, 6 cans/case; <b>NDC: 70074-0575-13</b>  2 fl. oz. nursettes, 48/case	<b>CHO:</b> corn maltodextrin, sucrose (powder); sucrose, modified tapioca starch (RTF) <b>PRO:</b> enzymatically hydrolyzed casein , L-amino acids <b>FAT:</b> high oleic safflower (powder), safflower (RTU), MCT, soy, M. alpina and C. cohnii oils <b>Vitamins, minerals</b> 20 cal./fl.oz. <b>Osmolality</b> =320 mOsm/kg H <sub>2</sub> O (powder), 370 mOsm/kg H <sub>2</sub> O (RTF)	Infants with severe food allergies, sensitivity to intact protein, protein maldigestion or fat malabsorption; management of short gut syndrome, cystic fibrosis, and severe diarrhea	<b>Non-breastfed infants</b>			
					<b>Powder:</b> 16 oz.	7 cans	8 cans	6 cans
						26 cans	28 cans	20 cans
					<b>RTF (2 oz.)</b>	416 nursettes	448 nursettes	320 nursettes
					<b>Partially breastfed infants</b>			
					<b>Powder:</b> 16 oz.	3 cans	4 cans	3 cans
					<b>RTF (32 oz.)</b>	12 cans	14 cans	10 cans
					<b>RTF (2 oz.)</b>	192 nursettes	224 nursettes	160 nursettes

Hypoallergenic Formulas—Elemental Formulas								
Product Name	Description	Packaging	Composition	Indications	Maximum Monthly WIC Issuance Amounts			
<b>Elecare® with DHA and ARA</b> (Abbott Nutrition)	A nutritionally complete amino acid based infant formula.  <b>Milk Protein Free Lactose Free Gluten Free Soy Protein Free Fructose Free Galactose Free Halal</b>	<b>Powder:</b> 14.1 oz can; 6 cans/case (use unpacked level scoops) <b>Can yield: 95 fl. oz.</b>  <b>NDC: 70074-0535-11</b>	<b>CHO:</b> corn syrup solids <b>PRO:</b> Free L-amino acids <b>FAT:</b> high oleic safflower, MCT and soy, M. alpina and C. cohnii oils  <b>Vitamins, minerals</b> 20 cal/fl. oz. (Osmolality = 350 mOsm/kg H <sub>2</sub> O)	For infants who cannot tolerate intact protein; designed for the management of maldigestion, malabsorption, severe food allergies, GI tract impairment and other conditions requiring an elemental diet. <b>Specialist intervention required.</b>	<b>Non-breastfed infants</b>			
					<b>0-3 months</b>	<b>4-5 months</b>	<b>6-11 months</b>	
					<b>Powder:</b> 14.1 oz. 20 cal/oz	9 cans	10 cans	7 cans
					<b>Partially breastfed infants</b>	<b>1-3 months</b>	<b>4-5 months</b>	<b>6-11 months</b>
<b>Powder:</b> 14.1 oz. 20 cal/oz	3 cans	4 cans	3 cans					
<b>Elecare Jr.</b> (Abbott Nutrition)	A nutritionally complete amino acid based medical food.  <b>Milk Protein Free Lactose Free Gluten Free Soy Protein Free Fructose Free Galactose Free Halal</b>	<b>Powder:</b> 14.1 oz can; 6 cans/case (unflavored, vanilla) (use unpacked level scoops) <b>Can yield: 62 fl. oz.</b>  <b>NDC:</b> <b>Unflavored: 70074-0552-54</b>  <b>Vanilla: 70074-0565-86</b>	<b>CHO:</b> corn syrup solids <b>PRO:</b> L-amino acids <b>FAT:</b> high oleic safflower, MCT and soy oils, DATEM  <b>Vitamins, minerals</b> 30 cal/fl. oz. (Osmolality = 590 mOsm/kg H <sub>2</sub> O)	For children $\geq 12$ months who cannot tolerate intact or hydrolyzed protein; designed for the management of protein maldigestion, malabsorption, severe food allergies, GI tract impairment and other conditions requiring an elemental diet. <b>Specialist intervention required.</b>	<b>Children</b>			
					<b>Powder</b> 14.1 oz.	14 cans		

Hypoallergenic Formulas—Elemental Formulas								
Product Name	Description	Packaging	Composition	Indications	Maximum Monthly WIC Issuance Amounts			
<b>E028 Splash</b> (Nutricia North America)	Nutritionally complete synthetic amino acid diet.  <b>Lactose Free            Gluten Free            Casein, Whey, and Milk Protein Free            Soy Protein Free</b>	<b>Ready to feed:</b> 8 fl. oz. drink boxes, 27 drink boxes/case (orange pineapple, grape, tropical fruit)  <b>NDC:</b> <b>Grape: 49735-0126-70</b> <b>Tropical Fruit: 49735-0126-66</b> <b>Orange-Pineapple: 49735-0110-50</b>	<b>CHO:</b> maltodextrin, sucrose; corn syrup solids (orange-pineapple only) <b>PRO:</b> L-amino acids <b>FAT:</b> Fractionated coconut, MCT, canola and high oleic sunflower, palm kernel oils  <b>Vitamins, minerals</b> 29.6 cal./fl.oz <b>Osmolality = 820</b> mOsm/kg H <sub>2</sub> O	Provides complete or supplemental nutritional support for children with severe GI impairment. <b>Specialist intervention required.</b>	<b>Children</b>			
					<b>RTU</b> 8 oz.	113 boxes		
<b>Neocate® Infant with DHA and ARA</b> (Nutricia North America)	Nutritionally complete, elemental formula with DHA and ARA which requires minimal digestion.  <b>Lactose Free            Sucrose Free            Milk Free</b>	<b>Powder:</b> 14 oz. can, 4 cans/case (unflavored) (use unpacked scoops) <b>Can yield = 85 fl. oz. (mixed to 20 cal/fl. oz)</b>  <b>NDC: 49735-0125-95</b>	<b>CHO:</b> corn syrup solids <b>PRO:</b> L- amino acids <b>FAT:</b> MCT, palm kernel and/or coconut, high oleic sunflower, soy, sunflower, M. alpina and C. cohnii oils  <b>Vitamins, minerals</b> 20 cal./fl. oz. <b>Osmolality = 375</b> mOsm/kg H <sub>2</sub> O	Infants with cow/soy milk protein allergy, multiple food protein intolerance, short bowel syndrome, eosinophilic esophagitis, or other medical conditions for which an amino-acid based formula is required. <b>Specialist intervention required.</b>	<b>Non-breastfed infants</b>			
					<b>Powder:</b> 14 oz.	<b>0-3 months</b> 10 cans	<b>4-5 months</b> 11 cans	<b>6-11 months</b> 8 cans
					<b>Partially breastfed infants</b>	<b>1-3 months</b>	<b>4-5 months</b>	<b>6-11 months</b>
					<b>Powder:</b> 14 oz.	5 cans	6 cans	4 cans

Hypoallergenic Formulas—Elemental Formulas								
Product Name	Description	Packaging	Composition	Indications	Maximum Monthly WIC Issuance Amounts			
<b>Neocate® Junior</b> (Nutricia North America)	Elemental medical food containing free amino acids.  <b>Lactose Free Galactose Free Milk Free Sucrose Free</b>	<b>Powder:</b> 14 oz. can, 4 cans/case (unflavored, tropical fruit, chocolate) <b>Can yield = 65 fl. oz. (unflavored), 60 oz. (flavored)</b>  <b>NDC:</b> <b>Unflavored: 49735-0117-90</b> <b>Tropical: 49735-0121-24</b> <b>Chocolate: 49735-0126-90</b>	<b>CHO:</b> corn syrup solids; sucrose (chocolate only) <b>PRO:</b> L-amino acids <b>FAT:</b> fractionated coconut, canola, high oleic safflower oils  <b>Vitamins, minerals</b> 30 cal/fl oz <b>Osmolality = 590</b> mOsm/kg H <sub>2</sub> O (unflavored); 680 mOsm/kg H <sub>2</sub> O (tropical fruit); 700 mOsm/kg H <sub>2</sub> O (chocolate)	Children with gastrointestinal impairment due to milk protein sensitivity or other medical conditions affecting the GI tract. <b>Specialist intervention required.</b>	<b>Children</b>			
					<b>Powder:</b> 14 oz Unflavored Flavored	14 cans 15 cans		
<b>Nutramigen® AA™/ PurAmino</b> (Mead Johnson Nutrition™)	Nutritionally complete, hypoallergenic, amino acid-based formula for infants and toddlers with severe cow's milk protein allergy and/or multiple food protein allergies.  <b>Gluten Free Lactose Free Galactose Free Sucrose Free</b>	<b>Powder:</b> 14.1 oz. can, 4 cans/case (use unpacked level scoops) <b>Can yield = 98 fl. oz. (mixed to 20 cal/fl. oz.)</b>  <b>NDC: 0087-129049 (Nutramigen AA)</b>  <b>NDC pending for PurAmino</b>	<b>CHO:</b> corn syrup solids, modified tapioca starch <b>PRO:</b> L-amino acids <b>FAT:</b> palm olein, soy, coconut, high oleic sunflower, M. alpina and C. cohnii oils  <b>Vitamins, minerals</b> 20 cal. /fl. oz. <b>Osmolality = 350</b> mOsm/kg H <sub>2</sub> O	Infants and toddlers with cow's milk protein allergy and multiple food protein allergies, including atopic dermatitis, diarrhea, vomiting, reflux, inflammation, or intestinal hyperpermeability, not effectively managed by an extensively hydrolyzed formula. <b>When used as a milk substitute, the total calcium content of the diet should be assessed.</b>	<b>Non-breastfed infants</b>			
					<b>0-3 months</b>	<b>4-5 months</b>	<b>6-11 months</b>	
					<b>Powder:</b> 14.1 oz.	8 cans	9 cans	7 cans
					<b>Partially breastfed infants</b>	<b>1-3 months</b>	<b>4-5 months</b>	<b>6-11 months</b>
<b>Powder:</b> 14.1oz.	4 cans	5 cans	3 cans					