



Policy Title New Jersey Infant Formula Mandate

Policy Number FS.CLIN.17

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy

Consideration for non-standard formula coverage is available only to infants enrolled in an AmeriHealth New Jersey plan that includes coverage for prescription drugs. In accordance with New Jersey Senate Bill 1839, specialized non-standard infant formula is covered when an infant is diagnosed as having multiple food protein intolerance that has not been responsive to trials of standard non-cow milk based formulas. Standard formulas include milk-based, soy-based, and milk-based lactose free products.

Specialized formulas for infants with metabolic disorders are not covered through the pharmacy benefit. Metabolic formulas are covered through the medical benefit.

The use of **Nutramigen®**, **Pregestimil®**, **Neocate®**, **Portagen®**, **Alimentum®**, **NeoSure®**, and **Similac® PM 60/40** requires prior authorization (i.e, Clinical Pharmacy and/or Medical Director review).

Policy Description

Coverage for non-standard formulas is subject to utilization review, including periodic review, of the continued medical necessity of the specialized infant formula. Under Senate Bill 1839, "infant" is defined as birth through age 12 months.

Policy Guideline Inclusion

Quantity limit is four cases for a 30-day supply per copay or co-insurance.

Nutramigen®, **Pregestimil®**, **Neocate®**, **Portagen®**, **Alimentum®**, **NeoSure®**, and **Similac® PM 60/40** are approved when **all** of the following inclusion criteria are met:

- Documentation that the infant is under 13 months old
- Documentation of a diagnosis of multiple food protein intolerance or any of the indications specified for the infant formula (see appendix)
- Documentation of a trial and failure with at least **two** or contraindication to all of the following standard formulas:
 - Milk-based product
 - Soy-based product
 - Milk-based lactose free product

APPROVAL LENGTH: Through member's age of 12 months

Policy Guideline Exclusion

Nutramigen®, **Pregestimil®**, **Neocate®**, **Portagen®**, **Alimentum®**, **NeoSure®**, and **Similac® PM 60/40** are denied when **any** of the following exclusion criteria are present:

- No documentation that the infant is under 13 months old
- No documentation of a diagnosis of multiple food protein intolerance or any of the indications

- specified for the infant formula (see appendix)
- No documentation of a trial and failure with at least **two** of the following standard formula products:
 - Milk-based product
 - Soy-based product
 - Milk-based lactose free product

Policy List of Applicable Drugs

Product	Indication(s)	Formula type
Enfamil Nutramigen	<ul style="list-style-type: none"> ● Feeding of infants and children sensitive to intact proteins of milk and of other foods ● Feeding of infants with severe or multiple food allergies ● Feeding of infants with colic, persistent diarrhea, or other gastrointestinal disturbances due to milk protein allergy ● Maintenance of nutrition during test or elimination diets ● Tube feedings for patients with food allergies ● Feeding of infants with galactosemia 	Hypoallergenic protein hydrolysate formula
Pregestimil	<ul style="list-style-type: none"> ● Intractable diarrhea ● Short gut syndrome ● Steatorrhea ● Cystic fibrosis ● Severe protein-calorie malnutrition 	Hypoallergenic protein hydrolysate formula with medium chain triglycerides (mct)
Neocate	<p>Rapidly relieves the symptoms of persistent and severe food allergy</p> <ul style="list-style-type: none"> - Multiple Food Protein Intolerance - Allergy to extensively hydrolysed formula (eHF) - Early onset food allergy - Food allergy during breast feeding - GER unresponsive to standard therapy - Allergic Colitis - Dietary related colic 	100% amino acid based hypoallergenic formulas
EleCare (non-vanilla)		Nutritionally

	For meeting the nutritional needs of children 1 year of age and older who need an amino acid-based medical food or who cannot tolerate intact protein, for the dietary management of maldigestion, malabsorption, severe food allergies, GI tract impairment, or other conditions in which an elemental (amino acid based) diet is required.	Complete Amino Acid-Based Medical Food
Portagen	<ul style="list-style-type: none"> ● Defect in the intraluminal hydrolysis of fat (decreased pancreatic lipase, decreased bile salts) ● Defective mucosal fat absorption (decreased mucosal permeability, decreased absorptive surface) ● Defective lymphatic transport of fat (ie, intestinal lymphatic obstruction) 	Nutritionally complete and formulated for infants and children under 2 years of age who do not efficiently digest or absorb conventional fat and the resulting long chain fatty acids.
Alimentum & Similac Expert Care Alimentum	As a nutritionally complete hypoallergenic formula for infants and as a supplemental beverage for children with severe food allergies, sensitivity to intact protein (including colic due to protein sensitivity), protein maldigestion or fat malabsorption.	Protein Hydrolysate Formula With Iron
Similac Neosure	Special formula for conditions such as prematurity	Infant Formula With Iron
Similac 60/40	For infants predisposed to or being treated for hypocalcemia due to hyperphosphatemia, or those with impaired renal function who would benefit from lowered mineral intake. Additional iron should be supplied from other sources.	Low-Iron Infant Formula
Similac Special Care 20 And Similac Special Care 24 (available with iron)	When a 20 Cal/fl oz or 24 Cal/fl oz feeding is desired for growing, low-birth-weight infants and premature infants. Very low-birth-weight infants are particularly susceptible to gastrointestinal complications; therefore, feeding should be initiated cautiously. Similac Special Care is designed to meet the nutrient needs of these infants up to a weight of 3600 g (8 lb).	Low-Iron Premature Infant Formula
NOT COVERED		
Similac	Intended for low birth weight infants as a	Whey protein

Human Milk Fortifier	nutritional supplement to add to preterm breast milk. Human milk can be fortified with Similac Human Milk Fortifier until the low birth weight infant reaches a weight of approximately 3600 g (8 lb) or as directed by a doctor.	formulation
Similac Natural Care	Designed to be mixed with human milk or to be fed alternately with human milk to low birth weight infants. Once enteral feeding is well established, Similac Natural Care can be added in increasing amounts to human milk, or alternated with human milk to assure that the infant's nutrient needs are fully met. Human milk can be fortified with Similac Natural Care until the low birth weight infant reaches a weight of approximately 3600 g (8 lb) or as directed by a doctor.	Low Iron 24 Cal/fl oz Human Milk Fortifier
EleCare Vanilla	For meeting the nutritional needs of children 1 year of age and older who need an amino acid-based medical food or who cannot tolerate intact protein, for the dietary management of maldigestion, malabsorption, severe food allergies, GI tract impairment, or other conditions in which an elemental (amino acid based) diet is required.	Nutritionally Complete Amino Acid-Based Medical Food
Enfamil Premature 20 or 24 and Enfamil Premature 20 or 24 with Iron	Feeding of rapidly growing low birth-weight infants.	Whey protein formulation

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

New Jersey Senate Bill 1839

Policy Link to Related Policies

Printed

11/05/2010 13:33:54

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