



INLAND EMPIRE HEALTH PLAN

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.

Drug: Infant Formula

Class: Nutritional Supplement

Formulary medication: N/A

Effective Date: January 2005, revised November 2006, July 2007, August 2008, August 2009

Policy/Criteria:

1. Standard Formulas given orally for normal infant nutrition **are not covered** unless at least one of the conditions below in item 3 is met. Formula request with no specific therapeutic need is not a covered benefit.
2. Standard infant formulas for normal infant nutrition are available through WIC. WIC covered formulas include Enfamil LIPIL with Iron, Enfamil ProSobee LIPIL, Enfamil LactoFree LIPIL, Enfamil Gentlease LIPIL, and Enfamil A.R. LIPIL.
To find the nearest WIC local agency, please call California State WIC Branch at 1-888-942-9675
County of Riverside Health Services Agency, Department of Public Health: 800-455-4942
San Bernardino County Department of Public Health: 909-387-8301
3. Conditions meeting criteria for authorizations include:
 - Inflammatory bowel disease ● Carcinoma of the GI Tract ● Short-bowel syndrome
 - Fistulas of the GI tract ● Pancreatitis and pancreatic insufficiency ● Malabsorption
 - Vascular disease of the small bowel ● Radiation and chemotherapeutic enteropathy
 - Enteral (tube) feeding ● Inborn errors of metabolism ● Food allergies and intolerances
 - AIDS/HIV with weight loss
4. **Indication for Soy-protein based formula** (Enfamil ProSobee, Similac Isomil Soy, Isomil Advance Soy):
 - a. Lactose intolerance, cow's milk allergy, or galactosemia.
 - b. IgE-associated symptoms of milk allergy, particularly after the age of 6 months.
5. **Indication for hypoallergenic infant formula** (Alimentum, Nutramigen):
 - a. Indicated for use by infants with existing allergic symptoms (see b, c, and d for the restriction).
 - b. IgE-associated allergy symptoms: angioedema, wheezing, and anaphylaxis.

- c. Non-IgE associated allergy symptoms: hemosiderosis, malabsorption with villous atrophy, eosinophilic proctocolitis, enterocolitis, esophagitis and colic.
 - d. Soy-protein based formula must be tried first for other IgE-associated symptoms such as rhinitis, urticaria, vomiting, and eczema.
6. Formulas for premature infants can be obtained for a maximum of 6 months up to 6 months of age. Premature infants are defined as those infants born at less than 37 completed gestational weeks. Formulas for premature infants include: Premie Enfamil, Neosure, and Similac Special Care.
- Special Amino Acid preparations such as Neocate, Neocate One Plus, Vivonex, Criticare HN, may be obtained if infant fails a trial of protein hydrolysate formula. Prior authorization can be obtained for a maximum of 6 months; each request must be accompanied by a documentation of recent failed trial of protein hydrolysate formula/soy formula.
7. Member's weight must be less than 25% of the median weight for age.
8. Physician must submit Nutritional Evaluation Form to IEHP for approval.

Clinical Justification:

According to American Academy of Pediatrics' Policy on "Soy Protein-based Formulas: Recommendations for Use in Infant Feeding"¹, the Committee on Nutrition recommended the followings:

1. Isolated soy protein-based formula has no advantage over cow milk protein-based formula as a supplement for the breastfed infant.
2. Soy protein based formulas are lactose-free, and they are appropriate for use in infants with galactosemia and hereditary lactase deficiency.
3. Isolated soy protein based formula is suitable for parents seeking a vegetarian-based diet for a term infant.
4. Isolated soy-protein based formulas are indicated when lactose intolerance has been documented. Previously well infants with acute gastroenteritis can be managed after rehydration with continued use of human breast milk or standard dilutions of cow milk-based formulas.
5. The routine use of isolated soy protein-based formula has no proven value in the prevention or management of infantile colic.
6. The routine use of isolated soy protein-based formula has no proven value in the prevention of atopic disease in healthy or high-risk infants.
7. Infants with documented cow milk protein-induced enteropathy or enterocolitis frequently are as sensitive to soy protein and should not be given isolated soy protein-based formula routinely.
8. Most infants with documented IgE-mediated allergy to cow milk protein will do well on isolated soy protein-based formula.
9. Soy protein based formulas are not designed or recommended for preterm infants who weigh <1800g.

The Committee on Nutrition of American Academy of Pediatrics also published a Policy on "Hypoallergenic Infant Formulas"². The recommendations are as follow:

1. Hypoallergenic formulas are intended for use by infants with existing allergic symptoms.
2. Soy formulas can be used first for infants with IgE-associated symptoms of milk allergy, particularly after the age of 6 months.
3. For the treatment of infants with non-IgE-associated syndromes, such as proctocolitis and enterocolitis, soy is not recommended because of higher prevalence of concomitant reactions between cow's milk and soy proteins (25-60%).

Reference:

1. Soy Protein-based Formulas: Recommendations for Use in Infant Feeding. AMERICAN ACADEMY OF PEDIATRICS. *Pediatrics* Vol. 101 No. 1 January 1998, pp. 148-153.
2. Hypoallergenic Infant Formulas AMERICAN ACADEMY OF PEDIATRICS. *Pediatrics* Vol. 106 No. 2 August 2000, pp. 346-349



INLAND EMPIRE HEALTH PLAN

INFANT/PEDIATRIC NUTRITIONAL EVALUATION FORM

TO BE COMPLETED BY PRESCRIBING PHYSICIAN ONLY
PLEASE FAX THIS FORM TO (909) 890-2058

Member Name: _____ **IEHP ID #:** _____

Member DOB: _____ **Nutritional Supplement Requested:** _____

Standard Infant Formulas for normal infant nutrition are not covered (Milk-based (Enfamil), Soy-based (Enfamil ProSobee), and Lactose-free (Enfamil LactoFree) are covered thru WIC, to find the nearest WIC local agency, please call California State WIC Branch at 1-888-942-9675; County of Riverside Health Services Agency, Department of Public Health: 800-455-4942; San Bernardino County Department of Public Health: 909-387-8301).

Please provide information below:

- If member needs Infant Formula/nutritional supplement due to medical conditions, please specify and provide documentation:

- ICD-9: _____
- Hypoallergenic infant formula (Alimentum, Nutramigen) will only be covered if soy-protein based formula has been tried, and with documented allergic symptoms:

- This baby has tried other infant formula/nutritional supplement _____ before and failed.

Please note that most infant formula requests are covered up to 1 year of age unless it is medically necessary (documentation required). Weight must be less than 25% of the median weight for age.

1. What is your estimate of the duration of need for the requested nutritional product by this patient?

2. How many cans/bottles/packets will this patient require per day/week/month? _____ per _____
3. What is the patient's current height and weight? **Height:** _____ ' _____ " **Weight:** _____ lbs.
 - a. Weight: _____% of median weight (weight must be less than 25% of the median weight for age)
 - b. How much weight lost: _____ lbs. Over what period of time: _____
4. Other comments: _____

Physician Signature: _____ Date: _____