Nutritional Supplement Infant Formula
Drug Class Monograph

Line of Business: Medical
Effective Date: February 17, 2016
Renewal Date: May 17, 2017

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 Therapeutic Subcommittee.

Policy/Criteria:

Physicians must provide medical justification for nutritional supplementation on the IEHP Prescription Drug Prior Authorization Request Form (RX PA). For information that may be necessary for nutritional supplementation justification, please review our IEHP Nutritional Evaluation Form (NEF).

1. **Standard infant formulas** are not a covered benefit.
   a. Standard infant formulas for normal infant nutrition are available through WIC. WIC covered formulas include Enfamil Infant, Enfamil ProSobee, Enfamil Gentlease, and Enfamil A.R.
   b. To find the nearest WIC local agency, please call California State WIC Branch at 1-888-942-9675
      1. County of Riverside Health Services Agency, Department of Public Health: 800-455-4942
      2. San Bernardino County Department of Public Health: 909-387-8301

2. **Hypoallergenic infant formula** (ex: Alimentum, Nutramigen):
   a. Less than 12 months of age, and ONE of the following:
      1. Allergy or hypersensitivity to cow milk protein, such as:
         • Severe IgE-associated allergy symptoms (ex: angioedema, wheezing, anaphylaxis, urticaria)
         • Non-IgE associated allergy symptoms (ex: persistent vomiting/diarrhea, eosinophilic proctocolitis, enterocolitis, esophagitis)
2. Intolerance to breast milk or infant formula

b. For liquid form, must meet one additional criteria of the following:
   1. Intolerance to hypoallergenic powdered product
   2. Born less than 34 week gestational
   3. Birth weight less than 1800 grams
   4. Currently diagnosed with immune function disorder

c. Nutramigen with Enflora LGG Powder is considered medically necessary up to 12 months of age, when meet all of the following:
   1. Current diagnosis of cow’s milk protein allergy or intolerance to breast milk or infant formula
   2. No immune function disorder
   3. Current body weight > 3500 grams
   4. Documented intolerance to other comparable covered hypoallergenic, extensively hydrolyzed products without probiotic

3. Nonallergenic infant formula (ex: Neocate, Elecare)
   a. Less than 12 months of age, and one of the following:
      1. Failure or contraindication to hypoallergenic infant formula
      2. Intolerance to breast milk or infant formula due to:
         • Cow’s milk protein or food protein allergy
         • Protein maldigestion or malabsorption
         • GI disorders (e.g. short bowel syndrome)
      3. Documented in hospital use prior to discharge, establishing the need for the product
      4. Documented clinical fat malabsorption or steatorrhea diagnosis not effectively addressed by breast milk, regular infant formula and hypoallergenic infant formula.

4. Premature enriched infant formula (ex: Neosure, Enfacare)
   a. Maximum approval up to 9 months after hospital discharge, limited to two-month authorization terms
   b. Products 20 or 22 kcal/oz: premature birth before 37 gestational weeks, or birth weight less than 3500 grams
   c. Products 24 or 30 kcal/oz: current weight less than 3500 grams

Note: Request beyond one year of age with medical justification (e.g. weight falls below the third percentile on growth chart) will be reviewed on case-by-case basis
5. **Human milk fortifier products (ex. Enfamil Human Milk Fortifier)**  
   a. Less than 12 months of age, current weight less than 3600 grams and one of the following:  
      1. Receiving only human milk and no other infant formula used at the same time  
      2. Combination of human milk and infant formula administered via a feeding tube  
      3. Combination of human milk and infant formula administered orally when one of the following is met:  
         - Infant is at risk for necrotizing enterocolitis  
         - Mother of infant is establishing milk supply  
         - Human milk intake is increasing

6. **Other Specialty Infant Products:**  
   a. Fat malabsorption products (e.g. Neocate Infant DHA ARA.), Renal products (Similac PM 60/40), Enfaport RTU  
      - Please confirm CCS eligibility  
      - Documented diagnoses including, but not limited to renal function impairment, short bowel syndrome, necrotizing enterocolitis, organ dysfunction or cystic fibrosis.  
      - If not already covered by CCS, approval will be granted.

7. **Emergency Request:**  
   a. A one-time emergency one month supply of therapeutic formulas is available for infants under age one who are currently on a therapeutic formula, in order to avoid disruption of regimen continuity, while IEHP conducts a medical necessity review.

**Infant Therapeutic Formulas:**

<table>
<thead>
<tr>
<th><strong>Hypoallergenic, Extensively Hydrolyzed Products, including but not limited to:</strong></th>
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<tbody>
<tr>
<td>Similac Expert Care Alimentum</td>
<td>Pregestimil</td>
<td>Nutramigen</td>
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<tr>
<th><strong>Non-Allergenic (Amino Acid Based), including but not limited to:</strong></th>
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<tbody>
<tr>
<td>EleCare</td>
<td>PurAmino</td>
<td>Neocate Infant DHA ARA</td>
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<th><strong>Premature and Low Birth Weight Products, including but not limited to:</strong></th>
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<tr>
<td>Similac Expert Care Neosure</td>
<td>Similac Special Care 24</td>
<td>Similac Special Care 30</td>
</tr>
<tr>
<td>Gerber Good Start Premature 30</td>
<td>Gerber Good Start Premature 20</td>
<td>Gerber Good Start Premature 24</td>
</tr>
<tr>
<td>Enfamil Premature iron 30</td>
<td>Enfamil Premature low iron 20</td>
<td>Enfamil Premature low iron 24</td>
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| Enfamil Premature iron 24 |
Clinical Justification:

*Department of Health Care Services Policy Letter 14-003: Enteral Nutrition Products*

- MCPs shall develop and implement written policies and procedures for providing enteral nutrition products for outpatient beneficiaries who meet the new Medi-Cal enteral nutrition service policy outlined in the Enteral Nutrition Products sections of the Medi-Cal Part 2 Pharmacy Provider Manual.

- MCPs are required to provide or arrange for all medically necessary Medi-Cal covered services, and to ensure that these services are provided in an amount no less than what is offered to beneficiaries under Medi-Cal fee-for-services.

Reference:


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<th>Change Control</th>
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<td><strong>Date</strong></td>
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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:_______________________________________________________________

☐ 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. For members older than 1 year of age and still requiring nutritional supplementation, a nutritional consultation may be required.

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 for age)
   b. How much weight lost:___________lbs. Over what period of time:_______________

4. Other comments:___________________________________________________________________

Physician Signature:___________________________ Date: __________________________