Miscellaneous

Specialty Infant Enteral Nutrition

Products covered under this section are for patients meeting the following medical conditions:

- prematurity
- low birth weight
- cow's milk protein allergy
- fat malabsorption
- renal disorders
- chylothorax or long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHAD)

Regular infant formula products as defined in the Federal Food, Drug and Cosmetic Act (FD&C Act) are not covered.

Authorizations for specialty infant enteral products are limited to a maximum 2 month term, except when noted.

Medical Criteria:

To be considered for authorization of specialty infant enteral nutrition products administered orally or through a feeding tube, the beneficiary must meet the criteria specific to the product and/or product type requested as listed below:

1. Premature and low birth weight products:
    a. Products 20 or 22 kcal/ounce are limited to beneficiaries born prior to 37 weeks gestation or birth weight less than 3500 grams
    b. Products 24 or 30 kcal/ounce are authorized for one month only per request and limited to current weight (at time of dispensing) less than 3500 grams
2. Human milk fortifier products:
    a. Authorization is limited to one month only per request for beneficiaries with current weight less than 3600 grams and meet one of the following:
        i. Receiving only human milk and no other infant nutrition product (formula) used at the same time.
        ii. Breast fed or receiving human milk in combination with infant nutrition product (formula) administered only through a feeding tube

iii. Breast fed or receiving human milk in combination with infant nutrition product (formula) administered orally when one of the following conditions is currently documented and met:

A. Infant is at risk for necrotizing enterocolitis

B. Mother of infant is establishing milk supply

C. Human milk intake is increasing

3. Extensively hydrolyzed products without probiotics: Patient must meet one of the criteria listed below. Product specific criteria may also apply.

a. Current diagnosis of cow's milk protein allergy (CMPA)

b. Severe food allergy indicating a sensitivity to intact protein

4. Extensively hydrolyzed products with probiotics: Patient must meet one of the above listed criteria (3a – b) AND all of the following:

a. No immune function disorder

b. Born full term (between 37 weeks and 42 weeks)

c. No indwelling venous catheters

5. Amino acid-based (100 percent) products without probiotics: Patient must meet one of the following:

a. Documented intolerance to breast milk or infant formula due to one of the following:

i. A clinical diagnosis of severe cow's milk protein allergy (CMPA), multiple food protein allergies, or eosinophilic GI disorder

ii. Protein maldigestion or malabsorption diagnosis where extensively hydrolyzed specialty infant products have tried and failed

iii. A clinical diagnosis of gastrointestinal (GI) disorders such as short bowel syndrome of GI impairment

b. Extensively hydrolyzed (semi-elemental) products are contraindicated

c. For initial request, documented in hospital use prior to discharge, establishing the need for the product. Must meet one of the other criteria for subsequent request.

d. Documented clinical fat malabsorption or steatorrhea diagnosis not effectively addressed by breast milk, regular infant formula and extensively hydrolyzed protein. Authorization may also be considered for fat malabsorption or steatorrhea as a secondary diagnosis associated with cystic fibrosis, short-bowel syndrome or other related clinical conditions.

6. Amino acid-based (100 percent) products with probiotics: Patient must meet one of the above listed criteria (5a – d) AND all of the following:
    a. No immune function disorder
    b. Born full term (between 37 weeks and 42 weeks)
    c. No indwelling venous catheters or post-pyloric feeding type
7. Renal products,: Patient must meet one of the following:
    a. Renal function impairment
    b. Hypercalcemia
    c. Hypocalcemia due to hyperphosphatemia
8. Chylothorax or LCHAD deficiency product type (Enfaport): Patient must have one of the following documented diagnoses:
    a. Chylothorax
    b. Long-chain-3-hydroxyacyl-CoA-dehydrogenase deficiency (LCHAD deficiency)
    c. Cystic Fibrosis
    d. Mitochondrial disorder

Product Formulation Limitation

For liquid formulation, patient must meet one of the following:

1. Born less than 34-week gestation
2. Birth weight less than 1800 grams
3. Currently diagnosed with immune function disorder
4. Documented intolerance to equivalent powder formulation, if commercially available.

Product Age Limitations

Specialty infant products are restricted for use at time of birth through age 12 months except when one of the following criteria has been met:

1. Corrected age (CA) applies only to infants born prior to 37 weeks gestation. For example, if birth date is 36 weeks gestation (four weeks early), remove four weeks from actual age (AA) since birth to get CA. CA is always younger than AA.
2. Use beyond age 12 months (including CA when applicable) requires documented medical justification clearly supplied on, or with, the authorization request, as documented in the infant's medical record.

Maximum age at time of authorization is nine months plus 29 days; CA applies, except when noted.

Note: Quantities for specialty infant enteral nutrition products based on sole source nutrition are approved up to six months of age except infants that do not make expected progress in advancement to solid foods, usually associated with a lessening in kcals/kg of body weight need recognized by American Academy of Pediatrics. Additional medical documentation, stated clearly on or with the authorization request, as documented in the infant's medical record is required.