



Inland Empire Health Plan

Drug Class Prior Authorization Criteria Nutritional Supplement Infant Formula

Line of Business: Medicaid

P & T Approval Date: June 11, 2021

Effective Date: June 18, 2021

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.

Background:

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).

Specialty infant formula indicated for specific diagnosis or conditions are a Medicaid covered benefit when they are used in a therapeutic regimen that preclude the full use of regular food. IEHP provides coverage for all medically necessary Medi-Cal covered enteral nutrition products, and to ensure that these services are provided in an amount no less than what is offered to beneficiaries under Medi-Cal fee-for-service.

Please see the following link for the complete list of products that are offered by Medi-Cal fee-for-service: https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/enteral_a04p00.doc

STANDARD INFANT FORMULA

- a. Standard infant formulas are not a covered benefit.
- b. 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.
- c. 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



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NUTRAMIGEN, SIMILAC ALIMENTUM

Covered Uses: All FDA-approved indications

Exclusion Criteria: N/A

Required Medical Information:

Must meet "1" of the following requirements:

- a. Documentation of cow's milk protein allergy
- b. Severe food allergy indicating a sensitivity to intact protein

Age Restrictions: Must be less than 12 months of age

Prescriber Restrictions: N/A

Other Criteria: Duration of therapy: Up to 12 months of age
Reauthorization Criteria: Use beyond 12 months of age requires documented medical justification (e.g. do not make expected progress in advancement to solid foods)

NUTRAMIGEN ENFLORA

Covered Uses: All FDA-approved indications

Exclusion Criteria: N/A

Required Medical Information:

Must meet all of the following requirements:

- a. Must meet "1" of the following requirements:
 1. Documentation of cow's milk protein allergy
 2. Intolerance to breast milk or regular infant formula
- b. No immune function disorders
- c. Born full term (between 37 weeks and 42 weeks)
- d. No indwelling venous catheters



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Age Restrictions:	Must be less than 12 months of age
Prescriber Restrictions:	N/A
Other Criteria:	Duration of therapy: Up to 12 months of age Reauthorization Criteria: Use beyond 12 months of age requires documented medical justification (e.g. do not make expected progress in advancement to solid foods)

ELECARE INFANT, NEOCATE INFANT

Covered Uses:	All FDA-approved indications
Exclusion Criteria:	N/A
Required Medical Information:	Must meet "1" of the following requirements: <ul style="list-style-type: none">a. Documented intolerance to breast milk or infant formula due to "1" of the following:<ul style="list-style-type: none">1. Severe cow's milk protein allergy, multiple food protein allergies or eosinophilic GI disorder2. Protein maldigestion or malabsorption diagnosis where extensively hydrolyzed specialty infant products have tried and failed3. Gastrointestinal disorders such as short bowel syndrome or GI impairmentb. Extensively hydrolyzed products are contraindicatedc. Documented in hospital use prior to discharge, establishing the need for the productd. 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.



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Age Restrictions: Must be less than 12 months of age

Prescriber Restrictions: N/A

Other Criteria: Duration of therapy: Up to 12 months of age
Reauthorization Criteria: Use beyond 12 months of age requires documented medical justification (e.g. do not make expected progress in advancement to solid foods)

NEOCATE SYNEO INFANT

Covered Uses: All FDA-approved indications

Exclusion Criteria: N/A

Required Medical Information: Must meet all of the following requirements:

- a. No immune function disorders
- b. Born full term (between 37 weeks and 42 weeks)
- c. No indwelling venous catheter or post-pyloric feeding type
- d. Must meet “1” of the following requirements:
 - 1. Documented intolerance to breast milk or infant formula due to “1” of the following:
 - i. Severe cow’s milk protein allergy, 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. Gastrointestinal disorders such as short bowel syndrome or GI impairment
 - 2. Extensively hydrolyzed products are contraindicated
 - 3. Documented in hospital use prior to discharge, establishing the need for the product



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4. 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.

Age Restrictions: Must be less than 12 months of age

Prescriber Restrictions: N/A

Other Criteria: Duration of therapy: Up to 12 months of age
Reauthorization Criteria: Use beyond 12 months of age requires documented medical justification (e.g. do not make expected progress in advancement to solid foods)

ENFACARE, ENFAMIL ENFACARE, ENFAMIL PREMATURE, SIMILAC NEOSURE, SIMILAC SPECIAL CARE

Covered Uses: All FDA-approved indications

Exclusion Criteria: N/A

Required Medical Information: Must meet "1" of the following requirements:
a. Products 20 or 22 kcal/ounce are limited to infants born prior to 37 weeks gestation or birth weight less than 3500 grams
b. Products 24 or 30 kcal/ounce are limited to current weight less than 3500 grams

Age Restrictions: Must be less than 12 months of age

Prescriber Restrictions: N/A



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Other Criteria: Duration of therapy: Up to 12 months of age; limited to two-month authorization terms except when noted
Reauthorization Criteria: Use beyond 12 months of age requires documented medical justification (e.g. do not make expected progress in advancement to solid foods)

SIMILAC HUMAN MILK FORTIFIER, ENFAMIL HUMAN MILK FORTIFIER

Covered Uses: All FDA-approved indications

Exclusion Criteria: N/A

Required Medical Information: Must meet all of the following requirements:

- a. Current weight less than 3600 grams
- b. Must meet "1" of the following requirements:
 1. Receiving only human milk and no other infant nutrition product used at the same time
 2. Breast fed or receiving human milk in combination with infant nutrition product administered only through a feeding tube
 3. Breastfed or receiving human milk in combination with infant nutrition product administered orally when "1" of the following is currently documented and met:
 - i. Infant is at risk for necrotizing enterocolitis
 - ii. Mother of infant is establishing milk supply
 - iii. Human milk intake is increasing

Age Restrictions: Must be less than 12 months of age

Prescriber Restrictions: N/A



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SIMILAC PM, ENFAPORT RTU

Covered Uses: Must meet "1" of the following documented diagnoses:

- Renal function impairment
- Hypercalcemia
- Hypocalcemia due to hyperphosphatemia
- Chylothorax
- Long-chain-3-hydroxyacyl-CoA-dehydrogenase deficiency (LCHAD deficiency)
- Cystic fibrosis
- Mitochondrial disorder

Required Medical Information: Must meet the following requirement:

- Confirmed diagnosis

Age Restrictions: Must be less than 12 months of age

Prescriber Restriction: N/A

Other Criteria: Duration of therapy: Up to 12 months of age
Reauthorization Criteria: Use beyond 12 months of age requires documented medical justification (e.g. do not make expected progress in advancement to solid foods)



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References:

1. DHCS Medi-Cal Provider Manual - Enteral Nutrition Products. Available at: <https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/enteral.pdf>. Accessed June 1, 2021.

Change Control		
Date	Change	RPH
06/01/2021	<ul style="list-style-type: none"> Added language from DHCS Provider Manual to include exceptions for maximum two-month term limit 	VM
05/07/2021	<ul style="list-style-type: none"> Renew with no change 	VM
08/28/2020	<ul style="list-style-type: none"> Renew with no change 	RR
05/15/2019	<ul style="list-style-type: none"> Renew with no change 	ND
02/20/2019	<ul style="list-style-type: none"> Added hyperlink to DHCS Provider Manual for a complete list of products covered by DHCS: https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/enteral_a04p00.doc 	ND
06/29/2018	<ul style="list-style-type: none"> Changed Format 	IK
05/16/2018	<ul style="list-style-type: none"> Reformatted document Adopted the following criteria from DHCS enteral nutrition policy: <ol style="list-style-type: none"> 1. Nutramigen Enflora: added requirement of no indwelling venous catheters 2. Elecare Infant and Neocate Infant: documented intolerance to breast milk or infant formula due to: <ul style="list-style-type: none"> o Eosinophilic GI disorder o Malabsorption diagnosis where extensively hydrolyzed specialty infant products have tried and failed 3. Added criteria for Neocate Syneo Infant 	HC
04/26/2019	<ul style="list-style-type: none"> Renew with no change 	JM