

Enteral Nutrition Products: Specialty Infant

This section lists nutrient-altered, specialty infant enteral nutrition products medically needed for use in 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 are not a benefit regardless of route of administration (tube or oral) and regardless of reduced iron content or thickened form. For additional help, refer to the *Enteral Nutritional Products: An Overview* section of this manual.

Specialty infant products listed in this section of the manual may be oral or tube fed (beneficiaries under EPSDT are exempt from the *Welfare and Institutions Code* (W&I Code), Section 14132 (ab) tube feeding limitation).

Authorization

A *Treatment Authorization Request* (TAR) or *Service Authorization Request* (SAR) is required for all enteral nutrition products.

Medical Criteria

In addition to the Prescription Requirement, Medical Criteria and Documentation Requirements listed in the *Enteral Nutrition: An Overview* section of this manual, the following medical criteria must be met and documented clearly on or attached to the authorization request to receive authorization for Medi-Cal reimbursement for all specialty infant enteral nutrition products.

- Product use limited to birth through age 12 months.
 - Corrected age (CA) applies to infants born prior to 37 weeks gestation.
 - ❖ CA example: If birth date is 36 weeks gestation (4 weeks early), remove 4 weeks from Actual Age (AA) since birth to get CA. CA is always younger than AA.
 - Note:** CA shall be used only when infant was born prior to 37 weeks gestation.
 - Product 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 9 months plus 29 days at time of authorization; CA applies, except when noted.
- Authorization is limited to a maximum 2 month term, except when noted.
- Quantities based on sole source nutrition are approved up to 6 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), require additional medical documentation, stated clearly on or with the authorization request, as documented in the infant's medical record.

Product Type Criteria

Specialty infant products authorized for Medi-Cal reimbursement are limited to the products listed and specified product numbers published in this manual section. Product number approved on a TAR or SAR shall be the same product number dispensed and billed.

Specialty infant enteral nutrition products are grouped by the product types listed below which are based on the manufacturer indications for use, age or corrected age (CA) of beneficiary, size of beneficiary, related caloric needs and accepted standards of practice.

For each of the following product types, additional criteria outlined in this section must also be met to receive authorization.

Specialty Infant Enteral Nutrition Product Types

- Premature and Low Birth Weight Products (Prem/LBW)
- Extensively Hydrolyzed Products (EH)
- 100% Amino Acid-Based Products (100% AA)
- Fat Malabsorption Products (Fat)
- Renal Products (Renal)
- Chylolthorax or Long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHAD deficiency)

BENEFICIARY AND PRODUCT LIMITATIONS TABLE

Premature and Low Birth Weight products

20 or 22 kcal/ounce

- Similac Expert Care Neosure powder or ready to feed (RTF), 20 kcal per ounce
- Enfamil Premature liquid with iron, or without iron, 20 kcal per ounce
- EnfaCare powder or ready to use (RTU), 22 kcal per ounce
- **Gerber Good Start Nourish powder or ready to feed (RTF), 22 kcal per ounce**

24 or 30 kcal/ounce

- Similac Special Care ready to feed (RTF), 24 or 30 kcal per ounce
- Enfamil Premature liquid, with iron, or without iron, 24 kcal per ounce

Human Milk Fortifier (HMF)

- Similac Human Milk Fortifier (HMF) powder

Beneficiaries are limited to:

For all premature and low birth weight products:

- Born prior to 37-weeks gestation, or
- Birth weight < 3500 gm, and
- All of the following shall accompany each request for authorization and re-authorization:
 - Weeks gestation
 - Current age
 - Birth weight
 - Current weight

AND

For 24 or 30 kcal per ounce products:

- Infants shall have a current weight less than 3500 grams, at the time of dispensing.

For HMF products:

- Infant shall be fully breast fed with no other infant nutrition product used at the same time; and
- Current weight less than 3600 grams at the time of dispensing (weight gain is expected to be 33–34 grams/day when calculating 31-day supply limits, to predict weight during an authorization term).

Product is limited to:

For 24 or 30 kcal per ounce products:

- A one-month maximum term per authorization and re-authorization request, before medical re-evaluation and new prescription is required.

For HMF products:

- A one-month maximum term per authorization and re-authorization request, before medical re-evaluation and new prescription is required.

BENEFICIARY AND PRODUCT LIMITATIONS TABLE (continued)

Extensively Hydrolyzed Products (“hypo-allergenic,” “semi-elemental”)

- Similac Expert Care Alimentum w/iron powder or liquid
- Nutramigen powder, or liquid concentrate, or ready to use (RTU) liquid
- Nutramigen Enflora-LGG powder
- Pregestimil powder

Beneficiaries are limited to:

- Current diagnosed cow’s milk protein allergy (diagnosis signed by a licensed prescriber must be on, or attached to, each request for authorization and re-authorization), or
- Current diagnosed breast milk or infant formula intolerance exists and is documented in the medical record (diagnosis signed by a licensed prescriber must be on, or attached to, each request for authorization and re-authorization)

AND-

Nutramigen with Enflora LGG Powder is authorized for reimbursement only when all of the following are documented and met (signed by licensed prescriber with prescriber’s contact information on the request) at each authorization :

- No immune function disorder, and
- Infant current body weight greater than 3500 grams, and
- Documented intolerance to all of the following comparable products without prebiotic
 - Similac Expert Care Alimentum powder (without prebiotic), or liquid when qualified, and
 - Nutramigen powder (without prebiotic) or liquid when qualified.

Product is limited to:

Powdered form is required.

Liquid form is authorized only when one or more of the following is met:

- Infant born at less than 34 weeks gestation (documentation must accompany each authorization and re-authorization request), or
- Birth weight was less than 1800 grams (documentation must accompany each authorization and re-authorization request), or
- Infant is currently diagnosed with immune function disorder (documentation must accompany each authorization and re-authorization request).

BENEFICIARY AND PRODUCT LIMITATIONS TABLE (continued)

100% Amino Acid Based Products (protein content is in the form of AA)

- EleCare Infant powder (not EleCare Junior)
- Neocate Infant powder (not Neocate Junior)
- Nutramigen Amino Acid powder or PurAmino Powder *(not Nutramigen powder)

Note: EleCare Junior and Neocate Junior products are not specialty infant products, and shall not be substituted for Infant versions of the same label name.

Beneficiaries are limited to:

100% AA based products are available only if:

- Extensively hydrolyzed (semi-elemental) products are documented as contraindicated, or
- In-hospital use, documented, established the need for product prior to discharge, or
- Other diagnosed breast milk or infant formula intolerance exists and is documented in the medical record.

Product is limited to:

No additional limits.

(See Medical Criteria in this section and in the *Enteral Nutrition Products: An Overview* section of this manual for documentation requirements).

* **Effective August 1, 2013**

BENEFICIARY AND PRODUCT LIMITATIONS TABLE (continued)

Fat Malabsorption Products

- EleCare Infant powder (not EleCare Junior)
- Pregestimil powder
- Neocate Infant powder (not Neocate Junior)

Note: EleCare Junior and Neocate Junior products are not specialty infant products, and shall not be substituted for Infant versions of the same label name.

Beneficiaries are limited to:

Diagnosed and documented fat malabsorption not effectively addressed by breast milk, regular infant formula, and extensively hydrolyzed protein products.

Product is limited to:

No additional limits.

BENEFICIARY AND PRODUCT LIMITATIONS TABLE (continued)

Renal Infant Products

- Similac PM 60/40 powder

Beneficiaries are limited to:

- Renal function impairment, documented, or
- Hypercalcemia, documented, or
- Hypocalcemia due to hyperphosphatemia, documented.

Product is limited to:

No additional limits.

BENEFICIARY AND PRODUCT LIMITATIONS TABLE (continued)

Chylothorax or LCHAD Products

- Enfaport ready to use (RTU) liquid

Beneficiaries are limited to:

- Chylothorax, or
- Long-chain 3-hydroxyacyl-CoA dehydrogenase deficiency (LCHAD deficiency)

Product is limited to:

No additional limits.

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SPECIALTY INFANT ENTERAL NUTRITION PRODUCTS

Premature and Low Birth Weight Products

<u>Product Label Name</u>	<u>Caloric density (kcal/g or ml)</u>	<u>Medi-Cal Billing Number</u>	<u>UPC Number (Item)</u>	<u>UPC Number (Case)</u>	<u>MAC per g or ml</u>	<u>EAC per g or ml</u>
Abbott: 1-800-558-7677						
Similac Expert Care Neosure powd 20cal (371g)	4.58	70074057431	070074574318	070074574301	0.0382	0.0398
Similac Expert Care Neosure RTF 20cal (946ml)	0.74	70074057456	070074574561	070074574554	0.0070	0.0091
Similac Special Care 24cal w/iron RTF (59ml)	0.86	70074059583	070074595832	070074595825	0.0150	0.0166
Similac Special Care 30 w/iron RTF (59ml)	0.86	70074056295	070074562957	070074562940	0.0235	0.0251
Similac Human Milk Fortifier (HMF) powder (0.9g)	3.89	70074054599	070074545998	070074545981	1.2271	1.2287
Gerber: 1-973-593-7500						
<u>Gerber Good Start Nourish RTF 22 cal (709 ml)</u>	<u>0.74</u>	<u>50000095630</u>	<u>050000956302</u>	<u>500000956609</u>	<u>0.0068</u>	<u>0.0084</u> †
<u>Gerber Good Start Nourish Powd 22 cal (357 g)</u>	<u>5.09</u>	<u>50000003860</u>	<u>050000038602</u>	<u>50000038619</u>	<u>0.0385</u>	<u>0.0401</u> †

† Effective January 1, 2014

† Dagger indicates new product or change to an entire table row

· Asterisk(s) indicate a change to individual table cell(s)

+ Product limitation(s) apply. See the Beneficiary and Product Limitations Table at the beginning of this section and refer to appropriate product type.

Premature and Low Birth Weight Products (continued)

<u>Product Label Name</u>	<u>Caloric density (kcal/g or ml)</u>	<u>Medi-Cal Billing Number</u>	<u>UPC Number (Item)</u>	<u>UPC Number (Case)</u>	<u>MAC per g or ml</u>	<u>EAC per g or ml</u>
Mead Johnson: 1-800-457-3550						
Enfamil Premature w/iron 20cal (59ml)	0.71	00087139241	300871392410	300871392014	0.0155	0.0171
Enfamil Premature low iron 20cal (59ml)	0.71	00087139441	300871394414	300871394018	0.0155	0.0171
Enfamil Premature low iron 24cal (59ml)	0.86	00087139141	300871391413	300871391017	0.0155	0.0171
Enfamil Premature w/iron 24cal (59ml)	0.86	00087139341	300871393417	300871393011	0.0155	0.0171
EnfaCare powder 22cal (363g)	4.90	00087001944	300870019448	300870019042	0.0385	0.0401
EnfaCare RTU 22cal (946ml)	0.79	00087128741	300871287419	300871287013	0.0068	0.0084

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Extensively Hydrolyzed Products (“hypo-allergenic,” “semi-elemental”)

<u>Product Label Name</u>	<u>Caloric density (kcal/g or ml)</u>	<u>Medi-Cal Billing Number</u>	<u>UPC Number (Item)</u>	<u>UPC Number (Case)</u>	<u>MAC per g or ml</u>	<u>EAC per g or ml</u>
Abbott: 1-800-558-7677						
Similac Expert Care Alimentum w/iron powder (454g)	5.07	70074057664	070074576640	070074576633	0.0600	0.0616
Similac Expert Care Alimentum w/iron RTF liquid (237ml)	0.71	70074057509	070074575094	070074575087	0.0097	0.0113
<u>Similac Expert Care Alimentum w/iron RTF liquid (946ml)</u>	<u>0.71</u>	<u>70074057513</u>	<u>070074575131</u>	<u>070074575124</u>	<u>0.0097</u>	<u>0.0113</u>
Mead Johnson: 1-800-457-3550						
Pregestimil powder (454g)	5.00	00087036701	300870367013	300870367211	0.0604	0.0620
Nutramigen powder (454g)	5.00	00087033801	300870338013	300870338211	NA	0.0616
Nutramigen concentrate liquid (384ml)	1.33	00087049801	300870498014	300870498113	0.0160	0.0176
Nutramigen RTU liquid (946ml)	0.71	00087049901	300870499011	300870499110	0.0087	0.0103
Nutramigen Enflora-LGG powder (357g)	4.87	00087123941	300871239418	300871239012	0.0602	0.0618

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100% Amino Acid Based Products

<u>Product Label Name</u>	<u>Caloric density (kcal/g or ml)</u>	<u>Medi-Cal Billing Number</u>	<u>UPC Number (Item)</u>	<u>UPC Number (Case)</u>	<u>MAC per g or ml</u>	<u>EAC per g or ml</u>
Abbott: 1-800-558-7677						
EleCare Infant powder (400g)	4.75	70074053511	070074535111	070074552514	0.0800	0.0816
Mead Johnson: 1-800-457-3550						
Nutramigen AA powder (400g)	4.90	00087129049	300871290495	300871290099	0.0722	0.0738
<u>PurAmino Powder</u>	<u>4.90</u>	<u>00087510478</u>	<u>300875104781</u>	<u>300875104811</u>	<u>0.0722</u>	<u>0.0738 †</u>
Nutricia North America: 1-800-365-7354						
Neocate Infant w/DHA ARA powder (400g)	4.21	49735012595	749735025956	749735125953	0.0744	0.0760

† **Effective August 1, 2013**

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Fat Malabsorption Products

<u>Product Label Name</u>	<u>Caloric density (kcal/g or ml)</u>	<u>Medi-Cal Billing Number</u>	<u>UPC Number (Item)</u>	<u>UPC Number (Case)</u>	<u>MAC per g or ml</u>	<u>EAC per g or ml</u>
Abbott: 1-800-558-7677						
EleCare Infant powder (400g)	4.75	70074053511	070074535111	070074552514	0.0800	0.0816
Mead Johnson: 1-800-457-3550						
Pregestimil powder (454g)	5.00	00087036701	300870367013	300870367211	0.0604	0.0620
Nutricia North America: 1-800-365-7354						
Neocate Infant w/DHA ARA powder (400g)	4.21	49735012595	749735025956	749735125953	0.0744	0.0760

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Renal, Infant Products

<u>Product Label Name</u>	<u>Caloric density (kcal/g or ml)</u>	<u>Medi-Cal Billing Number</u>	<u>UPC Number (Item)</u>	<u>UPC Number (Case)</u>	<u>MAC per g or ml</u>	<u>EAC per g or ml</u>
Abbott: 1-800-558-7677 Similac PM 60/40 powder (400g)	5.10	70074060850	070074608501	070074008509	0.0400	0.0416

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Chylolthorax or LCHAD Products

<u>Product Label Name</u>	<u>Caloric density (kcal/g or ml)</u>	<u>Medi-Cal Billing Number</u>	<u>UPC Number (Item)</u>	<u>UPC Number (Case)</u>	<u>MAC per g or ml</u>	<u>EAC per g or ml</u>
Mead Johnson: 1-800-457-3550						
Enfaport RTU (237ml)	1.07	00087128941	300871289413	300871289017	0.0104	0.0120

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