

Attachment #3

NEW JERSEY DEPARTMENT OF HEALTH WIC SERVICES

POLICY AND PROCEDURE MANUAL

Policy & Procedure Number: 2.15
Effective Date: November 26, 2014

Functional Area: II. NUTRITION SERVICES

Subject: WIC Contract Infant Formula

A. POLICY:

1. The issuance of low iron formulas, cow's milk, goat's milk, soy milk and rice milk for infants is not allowed and may have significant health consequences. The New Jersey WIC Program provides iron-fortified milk- and soy-based formulas. A bid/contract system is used to determine which brand of these infant formulas will be used.
2. The current contract iron-fortified milk- and soy-based infant formulas are:

ENFAMIL INFANT, ENFAMIL GENTLEASE and ENFAMIL PROSOBEE Produced by Mead Johnson

- a. A request form for Enfamil Infant, Enfamil Gentlease and Enfamil Prosobee is not needed for infants.
 - b. Medical documentation for these formulas is needed for women and children.
3. Non-contract, iron-fortified milk- and soy-based formulas are not provided by the New Jersey WIC Program unless there is a documented qualifying condition.

B. PROCEDURES:

1. Local Agency staff should inform applicants, participants (especially pregnant women), health care providers, and hospitals in their area on an ongoing basis that the New Jersey WIC Program provides only WIC contract milk- and soy-based formulas, Mead Johnson Enfamil Infant, Enfamil Gentlease and Enfamil Prosobee, for healthy babies whose mothers choose not to breastfeed or who partially breastfeed.
2. The State Agency will perform the initial notification to health care providers prior to the implementation of a new infant formula rebate contract.

3. Participants, who, due to religious beliefs require a kosher formula, can use Enfamil Infant or Enfamil Gentlease, which are Kosher Dairy and bears the (U)-D symbol or Enfamil Prosobee, which is Pareve and bears the (U) Pareve symbol from the Kashruth Division of the Orthodox Union.
4. Local Agency staff may contact the State Agency Nutrition Services Unit staff for technical assistance and support in contacting physicians and participants who insist on non-contract standard milk-and soy-based formulas or low iron formula.
5. A written request for standard contract milk- or soy-based formulas for women and children shall be treated as a request for an exempt infant formula or WIC eligible nutritional (Policy and Procedure 2.16). Requests should be documented on the New Jersey WIC Services Medical Documentation Form for WIC Formulas and Approved Supplemental Foods (Attachment 2.16D (WIC-11). Copies of the medical documentation form should be placed in the WIC participant's file to document the need for the formula. Telephone requests are acceptable initially, but medical documentation is required within two weeks of original request.

References: 7CFR Part 246 Special Supplemental Nutrition Program for Women, Infants and children (WIC): Revisions in the WIC Food Packages; Final Rule. March 4, 2014

NEW JERSEY DEPARTMENT OF HEALTH
WIC SERVICES

POLICY AND PROCEDURE MANUAL

Policy & Procedure Number: 2.16
Effective Date: July 26, 2016

Functional Area: **II. NUTRITION SERVICES**

Subject: WIC Formulas (Exempt Infant Formulas, WIC Eligible Nutritionals, and WIC Approved Supplemental Foods)

A: POLICY:

1. Exempt infant formulas, non-contract brand infant formulas, WIC-eligible Nutritionals and WIC authorized supplemental foods are available through the WIC Program in well defined circumstances.

a. “Exempt infant formula” An exempt infant formula is an infant formula intended for commercial or charitable distribution that is represented and labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems ([21 CFR 107.3](#)). Prior to any company or person manufacturing and marketing a new exempt infant formula or any infant formula, certain practices, procedures and processes must be followed ([Section 412 of the Federal Food, Drug, and Cosmetic Act](#)). For exempt infant formulas, there are specific terms and conditions that must also be met ([21 CFR 107.50](#)).

b. “WIC Eligible Nutritionals” means certain enteral products that are specifically formulated to provide nutritional support for individuals with a qualifying condition, when the use of conventional foods is precluded, restricted, or inadequate. Such WIC – eligible nutritionals must serve the purpose of a food, meal, or diet (may be nutritionally complete or incomplete) and provide a source of calories and one or more nutrients; be designed for enteral digestion via an oral or tube feeding; and may not be a conventional food, drug, flavoring or enzyme. Table 4- Minimum Requirements and Specifications for Supplemental Food s, Federal Register/ Vol. 79, No. 42/ Tuesday, March 4, 2014/Rules and Regulations.

c. “Non-Contract Brand Formula” means all infant formula, including exempt infant formula, that is not covered by an infant formula cost containment contract awarded by that State agency.

d. “WIC approved supplemental food” includes infant cereal, infant food fruits and vegetables, milk and milk alternatives, cheese, eggs, canned fish, fruits and vegetables, breakfast cereal, whole wheat bread or other whole grains, juice, legumes and/or peanut butter.

2. WIC participants may be eligible to receive infant formula, exempt infant formulas, or WIC-eligible Nutritionals that have one or more documented qualifying conditions that

prevents or restricts the use of WIC contract infant formula or conventional foods that does not adequately address their special nutritional needs. The qualifying medical condition(s) must be determined and documented by a health care professional licensed to write medical prescriptions under New Jersey State law.

3. Exempt infant formula, infant formula or WIC-eligible Nutritionals may not be issued solely for the purpose of enhancing nutrient intake or managing body weight without an underlying qualifying condition. It must not be used merely as a caloric supplement to a regular diet unless medical complications prevent the participant from consuming adequate amounts of food. Additionally, it must not be used as a substitute for milk for participants who have food intolerance to lactose or milk protein that can be successfully managed with the use of one of the other WIC food packages.
4. It is the responsibility of the participant's health care provider to provide medical oversight and instruction to participants who are issued exempt infant formula, WIC-eligible Nutritionals and/or supplemental foods that require medical documentation. This responsibility cannot be assumed by personnel at the WIC State or local agency. However, it is the responsibility of the WIC competent professional authority (CPA) to ensure that only the amounts of supplemental foods prescribed by the participant's health care provider are issued in the participant's food package.
5. WIC formulas (infant formulas, exempt infant formula and WIC-eligible Nutritionals) are issued in concentrated liquid or powder physical forms. Ready-to-feed formulas are issued if the CPA determines and documents that
 - a. The participant's household has an unsanitary or restricted water supply or poor refrigeration;
 - b. The person caring for the participant may have difficulty in correctly diluting concentrated or powder forms;
 - c. The WIC infant formula is only available in ready-to-feed;
 - d. The ready-to-feed form better accommodates the participant's condition; or
 - e. The ready-to-feed form improves the participant's compliance in consuming the prescribed WIC formula.
6. With appropriate medical documentation, in lieu of infant foods (cereal, infant fruit and vegetables, and infant meat), infants greater than 6 months of age may receive exempt infant formula or WIC-eligible Nutritionals at the same maximum monthly allowance as infants ages 4 through 5 months of age of the same feeding option.
7. All apparatus or devices (enteral feeding tubes, bags and pumps) designed to administer WIC formulas are not allowable WIC costs.
8. With appropriate medical documentation, WIC participants who receive WIC formulas (exempt infant formulas, infant formulas and WIC-eligible Nutritionals) are also eligible to receive authorized WIC supplemental foods appropriate for their status.
9. Participants requiring WIC formula (exempt formula/WIC-eligible Nutritionals) only and approved WIC supplemental foods in addition to WIC formula, must submit a completed

New Jersey WIC Services Medical Documentation Request for WIC Formulas and WIC Approved Supplemental Foods (Attachment 2.16D) with a licensed health care provider's signature in advance of issuance. Medical documentation instructions and qualifying conditions are specified in Attachments 2.16D1 and 2.16D2.

10. The completed written form must be placed in the WIC participant's file to document the need for the exception.
11. Exempt infant formulas and WIC-eligible Nutritionals are allowed for the following medical conditions, but are not limited to:
 - a. Severe Food Allergies that require an elemental formula
 - b. Metabolic Disorders
 - c. Gastrointestinal Disorders
 - d. Mal-absorption disorders/syndromes
 - e. Premature birth
 - f. Failure to Thrive/severely underweight
 - g. Low birth weight
 - h. NG/Tube Fed
 - i. Oral/Motor Feeding Problems
 - j. Inborn Errors of Metabolism
 - k. Immune System Disorders
 - l. Life Threatening Disorders, diseases and medical conditions that impair ingestion, digestion, absorption or the utilization of nutrients that could adversely affect the participant's nutrition status. Examples of such disorders are, but not limited to, neuromuscular disorder, renal disease, endocrine disorder, chronic lung disease, liver disease, congenital heart disease, immunological disorder, hematological conditions, etc.
 - m. Religious Preference (for Halal formula requests only) *

B: PROCEDURE:

1. All request for WIC formulas (exempt infant formulas, infant formulas, WIC-eligible Nutritionals) and WIC approved supplemental foods with WIC formulas must be documented on a completed New Jersey WIC Services Medical Documentation Request for WIC Formulas and WIC Approved Supplemental Foods (Attachment 2.16D).
2. Requests for Halal formulas do not need to be documented on the Attachment 2.16D. The issuance of non-contract formula without medical documentation in order to meet religious eating patterns is based on federal regulations which permit this.
3. The CPA shall select Religious Preference in the Medical Exception screen and then Similac Advance- milk based or Similac Isomil Soy, Abbott (Ross) standard non-contract formulas will be available to choose for the participant. *
4. The **maximum** length of approved time for WIC formulas, and when appropriate WIC approved supplemental foods with WIC formulas, is three (3) months.

5. The **CPA** shall conduct a complete assessment as per Policy and Procedure 2.00. This assessment shall include a review of the diagnosis to ensure it is consistent with the formula requested; the medical history and past notes in the participant record, the current height and weight and changes (gains/losses) from past anthropometric data, diet history/recall, and other pertinent information presented by the caregiver or health care provider. When necessary the CPA shall contact the health care provider for additional information and/or clarification of documentation.
6. If the requested formula WIC-eligible /Nutritionals is a hypoallergenic formula (i.e., Alimentum, Nutramigen, Pregestimil), a high calorie formula (i.e., Neosure or Enfacare) for a premature infant or a follow-up request for a formula/ WIC-eligible Nutritionals for a tube fed participant, the CPA can make a determination without seeking additional assistance or approval from a CPA with a Master of Science degree in Foods and Nutrition or related field and/or a registered dietitian.
7. For all other exempt formula and WIC-eligible Nutritionals requests, the CPA, that does not possess a Master of Science degree in Foods and Nutrition or related field and/or a registered dietitian, must seek final approval from a local agency resource that meets these requirements.
8. The State WIC nutrition staff is available to provide technical assistance and formula approvals when local agency staff desire additional information or a master's level nutritionist or registered dietitian is unavailable.
9. The local agency WIC coordinator is responsible to establish agency specific procedures to ensure that their CPAs have access to masters prepared nutritionists and/or registered dietitians for technical assistance and formula approvals. The State Agency should be contacted for rare unauthorized infant formula requests.
10. The CPA must indicate on the New Jersey WIC Services Medical Documentation Request for WIC Formulas and WIC Approved Supplemental Foods (Attachment 2.16D), his or her name and if required, the name of the CPA who provided final approval of the WIC formula/WIC approved supplemental foods.
11. WIC coordinators are responsible for ensuring that this protocol is followed by all CPAs in their agency. WIC Formulas and when appropriate WIC approved supplemental food approvals must be monitored and checked for appropriateness, as well as, documentation compliance, at a minimum, on a quarterly basis.
12. During the biennial on-site review, the State WIC nutritionist will monitor the agency's adherence to this protocol. Failure to comply will result in an audit finding.
13. Requests must be placed in the WIC participant's file to document the need for WIC formulas, and WIC approved supplemental foods
14. Telephone orders may be acceptable for case by case situations with approval from the Masters prepared nutritionists or registered dietitian. Emailed or faxed copies of

completed documentation form should be sent and filed within two weeks. A dated alert should be placed in the participants file and deleted once the documentation is received.

15. Under no circumstances should a request for an exempt infant formula, WIC-Eligible Nutritionals, supplemental foods and/or milk alternatives be continued from one certification to the next without determining the need for continued issuance.

Attachments:

- 2.16A – New Jersey WIC Authorized Exempt Infant Formulas or WIC-Eligible Nutritionals
- 2.16B - Exempt Infant Formulas and Medical Guide for New Jersey WIC
- 2.16C – WIC Clinic Request Letter for Exempt Infant Formulas and WIC-Eligible Nutritionals
- 2.16D/1 New Jersey WIC Services Medical Documentation Request Form for WIC Formulas, and WIC Available as WIC-11 on New Jersey WIC website

Authorized Exempt Infant Formulas and WIC-Eligible Nutritionals

Formula (in alphabetical order)	WIC ACCESS Subcategory	Manufacturer	MS/RD Req'd	Must Use CAP	Forms Available	Available For Status:
Alimentum (Similac Expert Care)	Exempt Infant Formulas	Abbott	No	Opt	Pwdr, RTU	P, B, N, I, C
BCAD 1	Exempt Infant Formulas	Mead Johnson	Yes	Yes	Pwdr	I, C
BCAD 2	WIC-Eligible Nutritionals	Mead Johnson	Yes	Yes	Pwdr	P, B, N, C
Boost	WIC-Eligible Nutritionals	Nestles	No	Yes	RTU	P, B, N, C
Boost High Protein	WIC-Eligible Nutritionals	Nestles	No	Yes	RTU	P, B, N, C
Boost Kids Essential 1.5 Cal	WIC-Eligible Nutritionals	Nestles	No	Yes	RTU	C
Boost Kids Essential 1.5 Cal with Fiber	WIC-Eligible Nutritionals	Nestles	No	Yes	RTU	C
Bright Beginnings Soy Pediatric Drink	WIC-Eligible Nutritionals	PBM Products, Inc.	Yes	Yes	RTU	C
Cyclinex-1	WIC-Eligible Nutritionals	Abbott	Yes	Yes	Pwdr	I, C
Cyclinex-2	WIC-Eligible Nutritionals	Abbott	Yes	Yes	Pwdr	P, B, N, I, C
Elecare	WIC-Eligible Nutritionals	Abbott	Yes	Yes	Pwdr	I, C
Elecare Junior	WIC-Eligible Nutritionals	Abbott	Yes	Yes	Pwdr	C
Enfamil Enfacare	Exempt Infant Formulas	Mead Johnson	Yes	Yes	Pwdr	I, C
Ensure	WIC-Eligible Nutritionals	Abbott	No	Opt	Pwdr, RTU	P, B, N, C
Ensure Plus	WIC-Eligible Nutritionals	Abbott	No	Opt	RTU	P, B, N, C
EO28 Splash	WIC-Eligible Nutritionals	Nutricia	Yes	Yes	RTU	P, B, N, I, C
Gluterex-1	WIC-Eligible Nutritionals	Abbott	Yes	Yes	Pwdr	I, C
Gluterex-2	WIC-Eligible Nutritionals	Abbott	Yes	Yes	Pwdr	P, B, N, C
Good Start Gentle	Milk Based Formulas	Gerber	No	Opt	Pwdr, Conc, RTU	I, C
Good Start Soy *	Soy Based Formulas	Gerber	No	Opt*	Pwdr, Conc, RTU	I, C
Hominex-1	WIC-Eligible Nutritionals	Abbott	Yes	Yes	Pwdr	I, C
Hominex-2	WIC-Eligible Nutritionals	Abbott	Yes	Yes	Pwdr	P, B, N, C
I-Valex-1	WIC-Eligible Nutritionals	Abbott	Yes	Yes	Pwdr	I, C
I-Valex-2	WIC-Eligible Nutritionals	Abbott	Yes	Yes	Pwdr	P, B, N, C
KetoCal 3:1	WIC-Eligible Nutritionals	Nutricia	Yes	Yes	Pwdr	P, B, N, I, C
KetoCal 4:1 Liquid	WIC-Eligible Nutritionals	Nutricia	Yes	Yes	RTU	P, B, N, I, C

Effective April 2013, revised 11.2014 *Good Start Soy powder is not available thru CAP and limited at other NJ stores statewide.

MS/RD Req'd - final approval by a MS and/or RD required prior to issuance

Must Use CAP- Yes = must use warehouse for formula; Opt = optional/participant's choice and/or availability

Forms Available - Pwdr = powder; Conc = concentrate; RTU = ready to use

Authorized Exempt Infant Formulas and WIC-Eligible Nutritionals

Formula (in alphabetical order)	WIC ACCESS Subcategory	Manufacturer	MS/RD Req'd	Must Use CAP	Forms Available	Available For Status:
Neocate Junior	WIC-Eligible Nutritionals	Nutricia	Yes	Yes	Pwdr	I, C
Neocate with DHA/ARA	Exempt Infant Formulas	Nutricia	Yes	Yes	Pwdr	I, C
Neosure (Similac Expert Care)	Exempt Infant Formulas	Abbott	No	Opt	Pwdr, RTU	I, C
Nutramigen Enflora LGG	Exempt Infant Formulas	Mead Johnson	No	Opt	Pwdr	P, B, N, I, C
Nutramigen	Exempt Infant Formulas	Mead Johnson	No	Opt	Conc, RTU	P, B, N, I, C
Nutren Junior	WIC-Eligible Nutritionals	Nestles	No	Yes	RTU	C
Pediasure	WIC-Eligible Nutritionals	Abbott	No	Opt	RTU	P, B, N, I, C
Pediasure with Fiber	WIC-Eligible Nutritionals	Abbott	No	Opt	RTU	P, B, N, I, C
Pediasure Peptide 1.0	WIC-Eligible Nutritionals	Abbott	Yes	Yes	RTU	P, B, N, I, C
Pediasure 1.5 Cal	WIC-Eligible Nutritionals	Abbott	Yes	Yes	RTU	P, B, N, I, C
Peptamen	WIC-Eligible Nutritionals	Nestles	Yes	Yes	RTU	C
Peptamen Junior	WIC-Eligible Nutritionals	Nestles	Yes	Yes	RTU	C
Periflex Infant	WIC-Eligible Nutritionals	Nutricia	Yes	Yes	Pwdr	I
Periflex Jr.Plus	Medical Foods	Nutricia	Yes	Yes	Pwdr	C
PFD Toddler	Exempt Infant Formulas	Mead Johnson	Yes	Yes	Pwdr	I, C
PFD 2	WIC-Eligible Nutritionals	Mead Johnson	Yes	Yes	Pwdr	P, B, N, C
Phenylade 40 Citrus, 25g	WIC-Eligible Nutritionals	Applied Nutrition	Yes	Yes	Pwdr pouches	P, B, N, C
Phenyl Free 1	Exempt Infant Formulas	Mead Johnson	Yes	Yes	Pwdr	P, B, N, I, C
Phenyl Free 2	WIC-Eligible Nutritionals	Mead Johnson	Yes	Yes	Pwdr	P, B, N, I, C
Portagen	WIC-Eligible Nutritionals	Mead Johnson	Yes	Yes	Pwdr	P, B, N, I, C
Product 3232a	Exempt Infant Formulas	Mead Johnson	Yes	Yes	Pwdr	P, B, N, I, C
Pregestimil DHA/ARA	Exempt Infant Formulas	Mead Johnson	No	Opt	Pwdr	I, C
Propimex-1	WIC-Eligible Nutritionals	Abbott	Yes	Yes	Pwdr	I, C
Propimex-2	WIC-Eligible Nutritionals	Abbott	Yes	Yes	Pwdr	P, B, N, C
RCF	Exempt Infant Formulas	Abbott	Yes	Yes	Conc	P, B, N, I, C
Similac PM 60/40	Exempt Infant Formulas	Abbott	Yes	Yes	Pwdr	P, B, N, I, C
Similac Special Care	Exempt Infant Formula	Abbott	Yes	Yes	RTU	I

Effective April 2013, revised 11.2014 *Good Start Soy powder is not available thru CAP and limited at other NJ stores statewide.

MS/RD Req'd - final approval by a MS and/or RD required prior to issuance

Must Use CAP- Yes = must use warehouse for formula; Opt = optional/participant's choice and/or availability

Forms Available - Pwdr = powder; Conc = concentrate; RTU = ready to use

Authorized Exempt Infant Formulas and WIC-Eligible Nutritionals

Formula (in alphabetical order)	WIC ACCESS Subcategory	Manufacturer	MS/RD Req'd	Must Use CAP	Forms Available	Available For Status:
Advance 24 calorie with Iron						
Tolerax	WIC-Eligible Nutritionals	Nestles	Yes	Yes	Pwdr	P, B, N, I, C
TYROS 1	Exempt Infant Formulas	Mead Johnson	Yes	Yes	Pwdr	I, C
TYROS 2	WIC-Eligible Nutritionals	Mead Johnson	Yes	Yes	Pwdr	P, B, N, C
Vivonex Pediatric	WIC-Eligible Nutritionals	Nestles	Yes	Yes	Pwdr	P, B, N, I, C
Vivonex T.E.N.	WIC-Eligible Nutritionals	Nestles	Yes	Yes	Pwdr	P, B, N, I, C

Effective April 2013, revised 11.2014 *Good Start Soy powder is not available thru CAP and limited at other NJ stores statewide.

MS/RD Req'd - final approval by a MS and/or RD required prior to issuance

Must Use CAP- Yes = must use warehouse for formula; **Opt** = optional/participant's choice and/or availability

Forms Available - Pwdr = powder; Conc = concentrate; RTU = ready to use

NJ WIC Exempt Formulas/WIC-Eligible Nutritionals Medical Guide

Attachment 2.16B

Formula (in alphabetical order)	Intended Status*	Description/Indications
Alimentum (Similac Expert Care)	Infants Children	Hypoallergenic formula for infants with protein sensitivity. For children with severe food allergies, sensitivity to intact protein, protein mal-digestion or fat absorption. Powder contains corn product (RTU does not). RTU could be used for clients with corn allergies/sensitivity.
BCAD 1	Infants Toddlers	An isoleucine-, leucine, and valine-free dietary powder for the dietary management of Maple Syrup Urine Disease (MSUD).
BCAD 2	Children (3+ years old) Adults	An isoleucine-, leucine, and valine-free dietary powder for the dietary management of Maple Syrup Urine Disease (MSUD) or other inborn errors of branched chain amino acid metabolism.
Boost	Children Adults	Use for dietary management of a disease or condition when conventional food is precluded or restricted. USDA regulations prevent prescribing this product solely to increase calorie consumption.
Boost High Protein	Children Adults	Provides 15 g protein/8 oz. Use for dietary management of a disease or condition when conventional food is precluded or restricted. USDA regulations prevent prescribing this product solely to increase calorie consumption.
Boost Kids Essential 1.5 Cal	Children (1-13 years old)	Used when conventional food is precluded or restricted i.e. oral motor feeding problems, tube feedings, failure to thrive, injury or trauma, chronic illness, etc.
Boost Kids Essential 1.5 Cal with Fiber	Children (1-13 years old)	Used when conventional food is precluded or restricted i.e. failure to thrive, elevated caloric needs, volume intolerance, fluid restricted, etc.
Bright Beginnings Soy Pediatric Drink	Children	Complete nutritional support. Used when conventional food is precluded or restricted and child is allergic to cow's milk protein or lactose intolerant.
Cyclinex-1	Infants Toddlers	Non essential amino acid-free formula used for the dietary management of urea cycle disorder, gyrate atrophy of the choroid and retina or HHH syndrome.
Cyclinex-2	Children Adults	Non essential amino acid-free nutrition support used for the dietary management of urea cycle disorder, gyrate atrophy of the choroid and retina or HHH syndrome.
Elecare	Infants	An elemental formula for clients who need an amino acid-based medical food or who cannot tolerate intact or hydrolyzed protein. Used for the dietary management of protein maldigestion, malabsorption, severe food allergies, short bowel syndrome, eosinophilic GI disorders, and GI impairment.
Elecare Junior	Children (1+ years old)	An elemental formula for children age 1 year or older. It is for the dietary management of protein maldigestion, malabsorption, severe allergies, short bowel syndrome, eosinophilic GI disorders and GI-tract conditions that require an amino acid based diet.

This Attachment replaces 2.16B, May 2014

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*May be available for other statuses in WIC ACCESS

NJ WIC Exempt Formulas/WIC-Eligible Nutritionals Medical Guide

Attachment 2.16B

Formula (in alphabetical order)	Intended Status*	Description/Indications
Enfamil Enafacare	Infants	22 kcal/oz formula used for nutritional management of premature and low birth weight infants.
Ensure	Children Adults	Use for dietary management of a disease or condition when conventional food is precluded or restricted. USDA regulations prevent prescribing this product solely to increase calorie consumption.
Ensure Plus	Children Adults	Provides concentrated calories and protein. Use for dietary management of a disease or condition when conventional food is precluded or restricted. USDA regulations prevent prescribing this product solely to increase calorie consumption.
EO28 Splash	Children (1-10 years old)	Nutritionally complete non-allergenic 100% free amino acid medical food used in the treatment of gastrointestinal tract impairment, eosinophilic esophagitis, gastroesophageal reflux disease, & short bowel syndrome.
Glutarex-1	Infants Toddlers	Formula for the dietary management of glutaric aciduria type 1. Lysine- and tryptophan free.
Glutarex-2	Children (1+ years old) Adults	Medical food for the dietary management of glutaric aciduria type 1. Lysine- and tryptophan free.
Good Start Gentle	Infants	A 100% whey protein standard formula. Partially hydrolyzed for easy digestion and improved tolerance.
Good Start Soy	Infants	A soy based lactose free standard formula. Partially hydrolyzed protein for easy digestion.
Hominex-1	Infants Toddlers	A methionine-free formula for the dietary management of vitamin B6-non-responsive homocystinuria or hypermethionemia.
Hominex-2	Children (1+ years old) Adults	A methionine-free medical food for the dietary management of vitamin B6-non-responsive homocystinuria or hypermethionemia.
I-Valex-1	Infants Toddlers	A leucine-free formula for the dietary management of disorder of leucine catabolism.
I-Valex-2	Children (1+ years old) Adults	A leucine-free medical food for the dietary management of disorder of leucine catabolism.
KetoCal (available in KetoCal 3:1 and KetoCal 4:1-must specify ratio prescribed)	Children (1+ years old)	A nutritionally complete, ketogenic medical food for the dietary management of intractable epilepsy or other medical condition that requires a ketogenic diet. Must

This Attachment replaces 2.16B, May 2014

*May be available for other statuses in WIC ACCESS

NJ WIC Exempt Formulas/WIC-Eligible Nutritionals Medical Guide

Attachment 2.16B

Formula (in alphabetical order)	Intended Status*	Description/Indications
by physician on CAP order form)		specify 3:1 or 4:1 on CAP order form.
Neocate Junior	Children (1-10 years old)	Nutritionally complete hypoallergenic, amino acid based medical food used for the treatment of cow and soy allergies, multiple food protein intolerances, short bowel syndrome, eosinophilic esophagitis, & gastrointestinal tract impairment,
Neocate with DHA/ARA	Infants	Nutritionally complete hypoallergenic infant formula used for the treatment of cow and soy allergies, multiple food protein intolerances, short bowel syndrome, eosinophilic esophagitis, & gastroesophageal reflux disease,
Neosure (Similac Expert Care)	Infants	A 22 Cal/fl.oz. iron fortified formula for conditions such as prematurity.
Nutramigen Enflora LGG	Infants	A hypoallergenic formula with extensively hydrolyzed protein intended for use with infants who are allergic to the intact protein found in milk based and soy based formula. LGG is a probiotic that is added to the product.
Nutramigen Previously was Nutramigen Lipil	Infants	Hypoallergenic, lactose free, sucrose free formula used to treat sensitivity to intact proteins in cow's milk and soy formulas and galactosemia.
Nutren Junior	Children (1-13 years old)	Used when conventional food is precluded or restricted i.e. oral motor feeding problems, tube feedings. 50% whey protein and lactose- and gluten-free
Pediasure	Children (1-13 years old)	Used when conventional food is precluded or restricted i.e. oral motor feeding problems, tube feedings. USDA regulations prevent prescribing this product solely to increase calorie consumption.
Pediasure with Fiber	Children (1-13 years old)	Added fiber. Used when conventional food is precluded or restricted i.e. oral motor feeding problems, tube feedings. USDA regulations prevent prescribing this product solely to increase calorie consumption.
Pediasure Peptide 1.0 cal	Children (1-13 years old)	Especially designed for children with malabsorption, maldigestion and other GI conditions. Nutritionally complete peptide based product that can be used for oral or tube feeding. Suitable for lactose intolerance and is gluten free.
Pediasure 1.5 cal	Children (1+ years old)	A calorically dense formula for pediatric patients that need more calories in less volume. Can be used for tube or oral feeding. Suitable for lactose intolerance and is gluten free.
Peptamen	Children (10+ years old) Adults	Peptide-based elemental medical food used for dietary management of GI impairment (malabsorption, pancreatitis, short bowel syndrome, cystic fibrosis, Crohn's disease, etc.).
Peptamen Junior	Children (1-13 years old)	Peptide-based elemental medical food used for dietary management of GI impairment (malabsorption, pancreatitis, short bowel syndrome, cystic fibrosis,

This Attachment replaces 2.16B, May 2014

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*May be available for other statuses in WIC ACCESS

NJ WIC Exempt Formulas/WIC-Eligible Nutritionals Medical Guide

Attachment 2.16B

Formula (in alphabetical order)	Intended Status*	Description/Indications
		Crohn's disease, etc.).
Periflex Infant	Infants (up to 1 year old)	Phenylalanine –free powdered infant formula with iron, for the dietary management of phenylketonuria (PKU). This formula must be consumed in conjunction with a whole protein source in quantities prescribed by a dietitian of physician.
Periflex Jr. Plus	Toddlers and young children	Phenylalanine-free powdered medical food for the dietary management of Phenylketonuria (PKU). Meets protein requirements in lower volume.
PFD Toddler (previously PFD 1)	Infants Toddlers	Protein- and amino acid- free product to treat inborn errors of amino acid metabolism that require intake of special formulations of amino acids. PFD 1 supplies only carbohydrates, fats, vitamins and minerals.
PFD 2	Children Adults	Protein- and amino acid- free product to treat inborn errors of amino acid metabolism that require intake of special formulations of amino acids. PFD 2 supplies only carbohydrates, fats, vitamins and minerals.
Phenylade 40 Citrus, 25 g	Children (1+ yearsold) Adults	Phenylalanine-free drink mix that provides 10 gm of protein in each 25 gm. pouch. Nutritionally incomplete, formulated to reduce formula fatigue and support diet compliance.
Phenyl Free 1	Infants Toddlers	A phenylalanine-free formula for dietary management of phenylketonuria (PKU).
Phenyl Free 2	Children (3+ years old) Adults	A phenylalanine-free medical food for dietary management of phenylketonuria (PKU).
Portagen	Children Adults	A milk protein based with medium chain triglycerides (MCT) medical food used for dietary management of individuals with defective intraluminal hydrolysis of fat, mucosal fat absorption, and/or lymphatic transport of fat.
Product 3232a	Infants Children	A protein hydrolysate formula base used to treat disaccharidase deficiencies (lactase, sucrase, maltase) or other disorders of carbohydrate metabolism. Additional carbohydrate is needed for complete nutrition.
Pregestimil DHA/ARA (previously Pregestimil Lipil)	Infants	Used to treat fat malabsorption, steatorrhea and sensitivity to intact proteins due to cystic fibrosis, short bowel syndrome, intractable diarrhea and severe protein malnutrition. Uses mostly medium chain triglyceride (MCT) oil.
Propimex-1	Infants Toddlers	A methionine- and valine-free formula for dietary management of propionic or methylmalonic acidemia.
Propimex-2	Children (1+ years old)	A methionine- and valine-free medical food for dietary management of propionic or methylmalonic acidemia.

This Attachment replaces 2.16B, May 2014

*May be available for other statuses in WIC ACCESS

NJ WIC Exempt Formulas/WIC-Eligible Nutritionals Medical Guide

Attachment 2.16B

Formula (in alphabetical order)	Intended Status*	Description/Indications
	Adults	
RCF	Infants Toddlers	For use in the dietary management of infants with seizure disorders requiring a ketogenic diet. Lactose- and gluten-free. Soy protein based.
Similac PM 60/40	Infants	A formula with a lower mineral content. Used for dietary management of impaired renal function.
Similac Special Care 24 calorie with Iron	Infants	A 24 Cal/fl.oz. iron fortified formula for growing, low birth weight infants and premature infants.
Tolerax	Children Adults	Elemental very low fat medical food containing 100% free amino acids used in the dietary management of impaired digestion and absorption and specialized nutrient needs (i.e. food allergies).
TYROS 1	Infants Toddlers	A phenylalanine- and tyrosine-free, iron fortified formula to treat tyrosinemia (Type I and II).
TYROS 2	Children Adults	A phenylalanine- and tyrosine-free, iron fortified formula for dietary management of inborn errors of tyrosine metabolism including tyrosinemia (Type II).
Vivonex Pediatric	Children (1-13 years old)	100% free amino acid elemental formula used in the treatment of short bowel syndrome, malabsorption syndrome, Crohn's disease, intestinal failure, GI disorder related to AIDS, transitional feeding, etc.
Vivonex T.E.N.	Children Adults	Low fat 100% free amino acid elemental medical food used in the treatment of bowel resections, irradiated bowel, malabsorption syndrome, trauma/surgery, Crohn's disease, intestinal failure, pancreatic disorders, etc.

Name changes or new formula are highlighted red.

This Attachment replaces 2.16B, May 2014

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New Jersey Department of Health
WIC Services

**MEDICAL DOCUMENTATION FOR WIC FORMULA AND
APPROVED WIC FOODS FOR INFANTS, CHILDREN AND WOMEN**

WIC Clinic	Phone	Fax
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Please complete entire form. Fax the completed form to the WIC clinic or have your patient return the document to the WIC Clinic. Thank you!

PLEASE NOTE: It is the responsibility of the health care provider to provide close medical oversight and instructions to participants issued exempt infant formula, WIC-eligible Nutritionals and/or supplemental foods that require medical documentation. This responsibility cannot be assumed by personnel at the WIC State or local agency.

Re-authorization is required every three months.

- **No authorization is necessary for Enfamil Infant, Enfamil Gentlease and Prosobee. Documentation for Enfamil AR is requested, but not required.**

Patient Name (First and Last)	Current Height/Length:
Date of Birth	Current Weight:
Parent/Caregiver Name (First and Last)	Date

1. Formula Requested: _____
Amount Requested: ☐ Maximum Allowable OR ☐ _____ ounces/day (if formula)
Physical Form: ☐ Powder ☐ Concentrate
Intended Length of Use: ☐ 1 Month ☐ 2 Months ☐ 3 Months

2. Qualifying Condition(s) (Justifies the medical need.) **(Complete and submit Page 2 with this form.)**

3. Can patient receive supplemental (or other WIC) foods in addition to formula or medical food? ☐ Yes ☐ No
(If Yes, please check the foods below that your patient **CAN / IS** eating.)

Infants (6-11 months only):

- ☐ Infant Cereal ☐ Infant Vegetable or Fruit

Children and Women:

- ☐ Juice ☐ Breakfast Cereal ☐ Whole Wheat Bread or Other Whole Grains ☐ Eggs
☐ Vegetables and Fruits ☐ Milk or Milk Substitutes ☐ Legumes ☐ Canned Fish* ☐ Peanut Butter

Reasons/Instructions/Comments: _____

**Fully breastfeeding women, women partially breastfeeding multiple infants from the same pregnancy, women pregnant with multiple infants, and pregnant women who are mostly breastfeeding an infant are the only WIC participant categories eligible to receive these foods.*

Health Care Provider Name (Print)	☐ MD ☐ DO ☐ APN ☐ PA-C
Medical Office/Clinic	Telephone Number
Medical Office/Clinic Address	Fax Number
Health Care Provider Signature	Date

WIC OFFICE USE ONLY:

Reviewed by CPA Name:	☐ Approved # of months: _____ ☐ Disapproved	Date:	If required: MS and/or RD CPA Name:
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**MEDICAL DOCUMENTATION FOR WIC FORMULA AND
APPROVED WIC FOODS FOR INFANTS, CHILDREN AND WOMEN**

QUALIFYING CONDITIONS

(Please check appropriate Qualifying Conditions.)

Participant Category	Non-Qualifying Conditions	Qualifying Conditions
Infants (up to 12 months)	• Non-specific formula or food intolerance • Only condition is a diagnosed formula intolerance or food allergy to lactose, sucrose, milk protein or soy protein that does not require an exempt infant formula	☐ Severe food allergies ☐ Milk and soy allergies ☐ Metabolic disorders ☐ Gastrointestinal disorder ☐ Mal-absorption disorders ☐ Premature birth ☐ Failure to thrive/severely underweight ☐ Low birth weight ☐ NG/Tube Fed ☐ Oral/motor feeding problems ☐ Immune system disorders ☐ Life threatening disorders
Children (up to five years of age)	• Solely for the purpose of enhancing nutrient intake or managing body weight without an underlying condition • Lactose intolerance • Participant preference	☐ Severe food allergies ☐ Milk and soy allergies ☐ Metabolic disorders ☐ Gastrointestinal disorder ☐ Mal-absorption disorders ☐ Premature birth ☐ Failure to thrive/severely underweight ☐ Low birth weight ☐ NG/Tube Fed ☐ Oral/motor feeding problems ☐ Immune system disorders ☐ Life threatening disorders
Women	• Solely for the purpose of enhancing nutrient intake or managing body weight without an underlying condition • Lactose intolerance • Participant preference	☐ Severe food allergies ☐ Milk and soy allergies ☐ Metabolic disorders ☐ Gastrointestinal disorder ☐ Mal-absorption disorders ☐ NG/Tube Fed ☐ Oral/motor feeding problems ☐ Immune system disorders ☐ Life threatening disorders

New Jersey WIC Services

SAMPLE Local Agency Clinic Request Letter For

Medical Documentation of Need for WIC Formulas and WIC Approved Supplemental Foods

Date

Dear Healthcare Provider:

The New Jersey WIC Program provides Enfamil Infant, Enfamil Gentlease or Enfamil Prosobee for healthy infants from birth up to twelve months of age whose mothers choose not to breastfeed or who partially breastfeed. We appreciate your cooperative effort to promote breastfeeding as the preferred feeding method for all infants, and recommend fully breastfeeding for approximately the first 6 months of life, with continued breastfeeding along with food supplementation for at least 12 months and thereafter for as long as mutually desired by the mother and child.¹ Contracts with Mead Johnson Nutritionals for infant formulas provide a special price that helps the WIC Program serve more infants and children in the State. A request form is not required for these formulas for infants, but is required for other WIC formulas, medical foods and WIC approved supplemental foods based on a qualifying condition. Medical documentation is also required for children and women who have a qualifying condition for all WIC formulas, medical foods and approved supplemental foods.

If, in your professional judgment, an infant, child, or a pregnant, breastfeeding or non breastfeeding postpartum woman in your care requires an Authorized Exempt Infant Formula/WIC-Eligible Nutritionals or approved supplemental foods in addition to Authorized Exempt Infant Formula/WIC-Eligible Nutritionals please complete the medical documentation form. Only a completed form will be honored. If approved, the formula and/or approved supplemental foods will be provided for a maximum of three months at which time a re-evaluation of the WIC participant by the healthcare provider is required before the formula can be received.

Thank you for your cooperation and interest in good nutrition. Please call your local WIC clinic at _____ if you would like further information.

Sincerely,

WIC Nutritionist

¹ American Academy of Pediatrics Provisional Section on Breastfeeding. WIC Program. *Pediatrics*. 2001;108:1216-1217

**New Jersey Department of Health
Division of Family Health Services
WIC Services**

Food Package III- Participants with Qualifying Conditions

On December 6, 2007, the United States Department of Agriculture issued an interim rule revising the WIC food packages. A major change was to Food Package III – participants with qualifying conditions (currently children, women with special needs). Food Package III will now serve all participants, including infants, with qualifying conditions. Participants on Food Package III must be medically fragile. **Food Package III changes are effective October 1, 2009.** The attached table illustrates qualifying and non-qualifying medical conditions of Food Package III.

According to WIC federal regulation, for a participant to receive infant formula (children and women), exempt infant formula or WIC – eligible medical foods a health care professional licensed to write medical prescriptions must make a medical determination that the participant has a qualifying condition (see attached table). In addition, the health care professional must also indicate the amount of the infant formula, exempt infant formula or WIC – eligible medical foods needed per day and the length of time the prescribed WIC formula is required by the participant. The health care professional also must indicate any supplemental food restrictions or contraindications. A signature, date and contact information is also required. A medical documentation form was developed to capture the required information (see attached New Jersey WIC Services Medical Documentation form for Formula and Approved WIC foods for Infants, Children and Women).

Summary of required medical documentation:

- Medical determination of a qualifying condition
- Name of the prescribed WIC formula
- Quantity needed per day of prescribed WIC formula
- Length of time the WIC formula is required by the participant
- Indication of supplemental food restrictions or contraindications
- Signature of health care professional, date and contact information

**New Jersey Department of Health
Division of Family Health Services
WIC Services**

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