

SECTION: Food Delivery**SUBJECT: Connecticut WIC Approved Formulas, WIC Approved Foods, and Religious Preference Formulas**

Federal Regulations: § 246.2 and §246.16a (c)(1) and 246.10(d) (2) (i)

Background:

Like many hospitals and health maintenance organizations, the Connecticut WIC Program has a sole source contract for infant formulas to effectively manage resources. Additionally, WIC State agencies are required by Federal law to obtain a competitive bid on infant formula for cost containment¹.

Connecticut WIC Program holds part of multi-state contract (NEATO) with 5 other New England WIC Programs, 3 Indian Tribal Organizations (ITO's) and Abbott Laboratories® which saves taxpayer money. Non-contract standard infant formulas are purchased by the WIC Program at the retail price. Connecticut receives approximately a 100% rebate on Similac formulas purchased. Therefore, infants receiving a non-contract standard infant formula cost the Program, more than those infants on the WIC contract formula.

Many States including New York, Vermont, New Jersey, Virginia, Kansas and California do not approve or provide non-contract standard iron-fortified milk-and soy-based infant formulas to participants in order to contain costs and serve more nutritionally at-risk women, infants and children. **As of July 1, 2009, the Connecticut WIC Program no longer provides non-contract standard milk- and soy-based infant formula under any circumstances.**

POLICY

The Connecticut WIC Program promotes breastfeeding as the normal and optimal method to feed infants for at least the first year of life with a special emphasis on the health benefits derived by exclusive breastfeeding for the first six months. If infants do consume formula, the program supports the American Academy of Pediatrics (AAP) recommendation that all formula fed infants receive iron-fortified formula for the first year.

In accordance with the recommendation, the Connecticut WIC program has a sole source contract with Abbott Laboratories® to provide standard iron-fortified milk and soy based formulas - **Similac® Advance® and Similac® Soy Isomil®** for healthy infants from birth to twelve months of age whose mothers choose not to breastfeed or who partially breastfeed. Participants over the age of twelve

¹ Oliveira, Vic & Prell, Mark & Smallwood, David & Frazao, Elizabeth, 2004. "[WIC And The Retail Price Of Infant Formula](#)," [Food Assistance and Nutrition Research Reports](#) 33873, United States Department of Agriculture, Economic Research Service.

Oliveira, Victor and Davis, David E. (2006): *Recent Trends and Economic Issues in the WIC Infant Formula Rebate Program*. Published in: Economic Research Report 22 (2006)

months that require a supplemental formula are authorized to use any approved formulas with medical documentation on the State Approved Contract and Specialized Formulas/Medical Food Listing.

Women who make the decision to use formula should receive support in their decision and receive complete and accurate information regarding the proper preparation, use and storage of formula.
http://www.nal.usda.gov/wicworks/Topics/FG/Chapter4_InfantFormulaFeeding.pdf

Also, <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048694.htm> and in Spanish <https://www.fda.gov/ForConsumers/ConsumerUpdates/ConsumerUpdatesEnEspanol/ucm400411.htm>

All local agency staff should be trained about WIC formula policies and procedures and the infant formula contract. All staff can help assure parents of WIC infants that the WIC contract formula can be appropriately used with most generally healthy, full term infants.

The Program provides **in Food Package III** special and exempt infant formulas, such as protein hydrolysate, hypercaloric, elemental and metabolic infant formulas with an appropriate nutrition related ICD-10 medical diagnosis, **because the use of conventional food is precluded, restricted, or inadequate to address their nutritional needs.**

General symptoms such as fussiness, colic, spitting-up and constipation *will not* be acceptable justification for formula changes. Although small differences in protein, fat and carbohydrate exist among all standard formulas, there are no medically proven advantages to any of the brand name formulas. While health care providers and/or parents/guardians may have a personal preference for a particular brand of formula, funding constraints and WIC regulations limit the issuance of non-contract, special/exempt formulas only to participants with qualifying medical conditions.

Special Formula/WIC Approved Foods

Medical Documentation is required for the issuance of the following formulas and/or supplemental foods: See Food Delivery Policy 400-11 *Use of Medical Documentation Form* for more details.

- Any special or exempt infant formula
- Any formula that contains less than 20 kilocalories per fluid ounce standard dilution
- Any formula provided to a child or adult who receives Food Package III (must have a qualifying medical condition)
- Any WIC eligible medical food
- Any authorized supplemental foods issued to participants receiving Food Package III
- Any additional authorized tofu issued to women who receives Food Package V and VII that exceeds the maximum substitution rate

Ready to Feed (RTF) Formula Issuance

Ready-to-feed formulas may be authorized when the CPA determines and documents that one of the following conditions are met:

- 1) The participant's household has an unsanitary or restricted water supply or poor refrigeration
- 2) The person caring for the participant may have difficulty in correctly diluting concentrated liquid or powder forms
- 3) The WIC infant formula is only available in ready-to-feed.

In addition to those conditions, ready-to-feed formula may be issued in **Food Package III**:

- 1) If a ready-to-feed form better accommodates the participant's condition; or
- 2) If it improves the participant's compliance in consuming the prescribed WIC formula.

Ready-to-feed formula should be issued on a limited capacity and duration, unless the participant meets the conditions listed above. Personal preference is not an allowable condition for RTF formula issuance. The WIC Nutritionist should engage in communication with the Health Care Provider to determine the best form of formula that meets the needs of the participant. In specific cases, with appropriate documentation, RTF may be medically appropriate. These include:

- Risk 362- Developmental, sensory or motor delays interfering with the ability to eat (Autism with eating disturbances sensory-taste);
- Risk 353- Food allergies (hypersensitivity to powdered formula);
- Risk 352a and 352b- Nutrition related infectious diseases, acute and chronic that requires specialized formula in ready-to-feed form;
- Risk 358- Eating disorders that involve food aversion to the extent of putting at risk intake of essential nutrients

Local agencies should use the Formula Usage Report in CT-WIC to track, monitor and review the issuance of RTF formula. When a participant is issued RTF formula, the participant's condition should be re-assessed in a period not to exceed 3 months, and as the medical condition improves, transition back to a non-RTF formula.

Religious Preferences and Formula Issuance

Both contract standard formulas offered by the Connecticut WIC program **Similac Advance**[®] and **Similac**[®] **Soy Isomil**[®] meet the requirements for participants requesting a Kosher or Halal infant formula due to religious preference. Non-contract formulas will not be provided for religious reasons.

Labeling of Kosher/Pareve and Halal foods:

Letters or words printed next to the kosher certification symbol on food packages. These are added to inform the consumer of the product's kosher category.

Kosher categories are Meat (*Fleishig* in Yiddish, *Basari* in Hebrew), Dairy (*Milchig* in Yiddish, *Chalavi* in Hebrew) or neither meat or dairy (*Pareve* in Yiddish, *Parve* in Hebrew). According to Jewish Dietary Laws, meat and dairy food must be prepared and consumed separately, and pareve food can be eaten with either meat or dairy dishes.

Meat:

"Meat", "M" or "Glatt" printed near the kosher symbol on the food package indicates the product is kosher and contains some meat or meat derivative.

Dairy:

"Dairy" or "D" printed near the kosher symbol on the food package indicates the product is kosher and contains some milk or milk derivative.

Fish:

"F" printed near the kosher symbol on the food package indicates the product is kosher and contains fish ingredients.

Pareve:

"Pareve", "Parev", or "Parve" printed near the kosher symbol on the food package indicates the item is neither meat or dairy.

Passover:

"P" printed near the kosher symbol on the food package does not stand for pareve, but instead it means the product is kosher for Passover and all year round.

Furthermore, D-P means dairy and kosher for Passover and all year round. M-P or Glatt-P means meat and kosher for Passover and all year round. F-P means fish and kosher for Passover and all year round.

Definition of Halal

In Arabic, the word *halal* means permitted or lawful. Halal foods are foods that are allowed under Islamic dietary guidelines. According to these guidelines gathered from the Qu'ran, Muslim followers cannot consume the following:

- pork or pork by products
- animals that were dead prior to slaughtering
- animals not slaughtered properly or not slaughtered in the name of Allah
- blood and blood by products
- alcohol
- carnivorous animals
- birds of prey
- land animals without external ears

These prohibited foods and ingredients are called *haram*, meaning forbidden in Arabic.

Halal is One of the Most Humane Methods of Animal Slaughter

Muslims are taught through the Qu'ran that all animals should be treated with respect and well cared for. The goal is to slaughter the animal, limiting the amount of pain the animal will endure.

When an animal is slaughtered, the jugular vein is cut and the blood is allowed to drain from the animal. Muslims are prohibited from consuming animal blood.

Additional Resources

Refer to the [WIC Formula Resource webpage](#) for a complete listing of Approved Formulas and Medical Foods, along with formula product codes.

Definitions:

Contract Formulas: Effective October 1, 2016 the current contract formulas are Abbott Laboratories® iron-fortified milk- and soy-based formulas- *Similac® Advance®* and *Similac® Soy Isomi®*. These are standard infant formulas, which can be provided to most healthy, full-term infants. These formulas do not require a prescription². WIC provides formula in supplemental amounts and may not provide all that an infant needs for a given month. *Similac Sensitive®*, *Similac®* and *Total Comfort®* are standard formulas for mild tolerance approved in Connecticut that have been reformulated to 20 kcal/oz. and no longer require medical documentation for issuance. However, like all other cow's milk based formulas, these products should not be provided to anyone with a known or suspected milk allergy. Also, like other products containing lactose, this product is contraindicated when a totally lactose free diet is indicated. *Similac® for Spit Up®* is a standard formula reformulated to 20 kcal/oz. that requires medical documentation and a qualifying medical condition for issuance.

- **Non-contract brand standard milk- and soy- based infant formulas:** Are formulas **not** covered by the current NEATO infant formula contract. These include all standard iron-fortified infant formulas manufactured by Mead Johnson® and Nestle®). This list also includes generic and store brand formulas manufactured by PBM Nutritionals e.g. *Parent's Choice* (Walmart).
- **Special Medical Formula or Exempt Infant Formula** (WIC eligible nutritionals): Some infants or children have a medical diagnosis requiring a special medical formula such as protein hydrolysate, hypercaloric, elemental or metabolic. These formulas are authorized when a participant has a documented nutrition-related medical diagnosis. **"Special" or Exempt infant formula is** an infant formula that meets the requirements under Section 412(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 350a(h)) and the regulations at CFR parts 106 and 107. (WIC Regulations (http://edocket.access.gpo.gov/cfr_2010/janqtr/pdf/7cfr246.2.pdf) An exempt infant formula can be authorized for infants or children when a health care provider determines and documents that the infant or child has a medical diagnosis that restricts the use of standard formulas and requires formulas such as protein hydrolysate, hypercaloric, elemental or metabolic. The quantities prescribed should be appropriate for the participant's age and special medical needs. These formulas are authorized when a participant has a documented nutrition-related medical diagnosis.

² Child participants requiring contract formula past one year of age need a completed Medical Documentation Form.
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- **WIC-eligible Medical Food**³(WIC eligible nutritionals): Certain enteral products that are specifically formulated to provide nutritional support for individuals with a qualifying condition, when the use of conventional food is precluded, restricted, or inadequate. Such WIC-eligible medical foods 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. WIC eligible medical foods include many, but not all, products that meet the definition of a medical food in Section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360 ee (b)(3))

- **Food Package III** This food package is reserved for issuance to women, infants and child participants who have a documented **qualifying condition*** that requires the use of a WIC formula (infant formula, exempt infant formula or WIC-eligible medical food) because the use of conventional foods is precluded, restricted, or inadequate to address their special nutritional needs. Participants who are eligible to receive this food package must have one or more qualifying medical conditions, as determined by a health care professional licensed to write medical prescriptions under State law. *The **qualifying conditions** include but are not limited to premature birth, low birth weight, failure to thrive, inborn errors of metabolism and metabolic disorders, gastrointestinal disorders, malabsorption syndromes, immune system disorders, severe food allergies that require an elemental formula, and life threatening disorders, diseases and medical conditions that impair ingestion, digestion, absorption or utilization of nutrients that could adversely affect the participant's nutritional status. This food package may not be issued solely for the purpose of enhancing nutrient intake or managing body weight.

³ The following are not considered a WIC eligible medical food: Formulas used solely for the purpose of enhancing nutrient intake, managing body weight, addressing picky eaters or used for a condition other than a qualifying condition (e.g. vitamin pills, weight control products, etc.); medicines or drugs as defined by the Food, Drug and Cosmetic Act (21 U.S.C. 350a) as amended; enzymes, herbs, botanicals; oral rehydration fluids or electrolyte solutions; flavoring or thickening agents; and feeding utensils or devices (e.g., feeding tubes, bags, pumps) designed to administer a WIC-eligible formula. (WIC Regulations 246.10 Table 4. Footnote 1)