

Contract and Non-Contract Infant Formula**Policy No. NS- 210.02**

Effective date: October 29, 2018

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Policy

Infants participating in the Georgia WIC program who require a milk-based or soy-based infant formula shall be provided one of the contract formulas: Enfamil Infant, Enfamil ProSobee, or Enfamil Gentlease. Enfamil A.R. may be provided with the required Medical documentation. Any issuance of an authorized, non-contract infant formula requires appropriate medical documentation. All infant formulas, including contract formula, require medical documentation to be issued to a child participant.

Purpose

To ensure that participants needing standard milk-based and soy-based formula receive contract formula.

Procedures

- I. Issue a food package containing Enfamil Infant, Enfamil ProSobee, or Enfamil Gentlease to any infant requiring a milk-based or soy-based infant formula.

Authorize issuance for a request of Enfamil A.R, to participants who present with appropriate medical documentation and meet the following two conditions:

1. Diagnosis of gastroesophageal reflux disease (GERD); and,
2. Documentation of one of the following conditions:

Tube feeding, GERD surgery (fundoplication), risk or history of aspiration, weight loss, or poor weight gain (drop of at least one weight channel on growth chart). Note: If weight is not provided, issuance will be based on weight obtained at WIC clinic.

Refer to the [Medical Documentation Policy](#) for information regarding medical documentation requirements.

- II. Do not accept medical documentation for unapproved, non-contract milk-based, soy-based, or lactose reduced infant formulas. For information on the Georgia WIC Approved contract and non-contract infant formulas, please see the [Georgia WIC Formula Guide](#).

Authority

7 C.F.R. §§ 246.10 (d) and (e)

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Definitions/Supporting Documentation

Competent Professional Authority (CPA) – An individual on the local agency staff who is authorized to determine nutritional risk and prescribe supplemental foods. The following individuals may be authorized and trained to serve as a CPA: physicians, nutritionists (bachelor's or master's degree in Nutritional Sciences, Community Nutrition, Clinical Nutrition, Dietetics, Public Health Nutrition), registered dietitians, licensed dietitians, registered nurses, and physician assistants (certified by the National Committee on certification of Physicians Assistants or certified by the State medical certifying authority), or State or local medically trained health officials.

Contract Infant Formula – All infant formula (except exempt infant formulas) produced by the manufacturer awarded the infant formula cost containment contract.

Exempt Infant Formula – An infant formula that is 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).

Infant formula - Means a food that meets the definition of an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)) and that meets the requirements for an infant formula under section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) and the regulations at 21 CFR parts 106 and 107.

Local Agency (LA) – A public or private, nonprofit health or human service agency that provides health services, either directly or through contract.

Non-Contract Brand Infant Formula – All infant formula, including exempt infant formula, that is not covered by an infant formula cost containment contract awarded by the State agency and is not subject to rebates.

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. WIC-eligible nutritionals include many, but not all, products that meet the definition of medical food in Section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)).