

SECTION 7.9

Subject: Food Package for Infants, Women and Children with Qualifying Medical Conditions (Food Package 3)

References: 7 CFR 246.10

Policy: CPAs may issue WIC-eligible standard contract infant formula, exempt infant formula or WIC-eligible medical foods to women, infants, and children who have a documented qualifying medical condition that requires the use of a WIC formula because the use of conventional food is precluded, restricted, or inadequate to address their special nutritional needs. Supplemental foods also may be issued in conjunction with medical formula with adequate medical documentation.

Purpose: To assure participants receive the WIC-eligible medical formulas and supplemental foods that meet their medical and/or nutritional needs and will be used by the participant.

Definitions:

Exempt infant formula: An exempt infant formula intended for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems.

Medical food: The term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

Procedures:

- **Processing Formula Requests:**
 - Local agencies must designate a CPA (preferably a Registered Dietitian) to serve as the lead person in the agency for processing and overseeing of Food Package 3 requests.
 - The lead person should ensure that all CPAs are trained on the appropriate use of specific formulas and maximum amounts allowed; are aware of new products, including product formulation changes; and product availability.
- **Issuance Requirements:**
 - Participants who are eligible to receive this food package must have one or more qualifying conditions as determined by a Health Care Professional licensed to write medical prescriptions. Food Package 3 provides:
 - Infants with exempt infant formula.
 - Children with standard contract infant formula, exempt infant formula or WIC-eligible medical food and allowable WIC foods.
 - Women with WIC-eligible medical food and allowable WIC foods.

- Supplemental Foods if included in the Health Care Provider's prescription. Refer to [Food Package 3 Reference Guide](#). For infants, see table below.
- For qualifying conditions (and non-qualifying) and medical documentation requirements, see [Section 7.6, Medical Documentation](#) and [Exhibit 7-D, Medical Documentation form](#).
- Infants birth through 11 months:
 - Issue the food package as indicated in the tables below. Refer to the [Formula Amounts Guide](#) for the allowed quantities of each formula.
 - Maximum formula quantities vary by breastfeeding status and by age.
 - CPAs must tailor the food packages accordingly. To support milk supply and infant health, only the minimal amount of formula needed (as determined by assessment) should be provided for infants who are breastfed.
 - Prescriptions for specialized premature formulas for *very premature infants* may only be approved 1 month at a time, e.g., Human Milk Fortifier, Similac Special Care 20/24, Enfamil Premature LIPIL 20/24.
- Infants 6 months of age or older:
 - Infants receiving exempt infant formula must have medical documentation for issuance of complementary foods. Medical documentation must be obtained prior to issuance of complementary food.
 - Infants, whose medical condition prevents them from consuming complementary infant foods, are eligible to receive a larger quantity of exempt infant formula. See tables below.
 - The increased quantity is equal to the monthly allowance for infants 4 through 5 months of age with the same feeding option.
 - This applies to exempt (medical) formula only. It does not apply to standard formula.
- Children 1-4 years of age:
 - Issue the food package as indicated in the tables below. The [Medical Formula Amounts Guide](#) and [Contract Formula Amounts Guide](#) list the allowed quantities of each formula.
 - Children may receive whole or 2% milk if indicated as appropriate by the Health Care Provider on the medical documentation form.
 - 32 oz. infant cereal or 36 oz. regular breakfast cereal is available for children 1-4 years of age. Issue the appropriate type of cereal based on the child's developmental abilities.
- Women:
 - Issue the food package as indicated in the tables below. The [Formula Amounts Guide](#) lists the allowed quantities of each formula.
 - Women may receive whole or 2% milk if indicated as appropriate by the Health Care Provider on the medical documentation form.

- **This food package may not be provided for:**
 - Solely for the purpose of enhancing nutrient intake or managing body weight without an underlying qualifying medical condition.
 - Infants whose only condition is:
 - A diagnosed formula intolerance or food allergy to lactose, sucrose, milk protein or soy protein that does not require the use of an exempt formula;
 - A non-specific formula or food intolerance
 - Women and children who have a food intolerance to lactose or milk protein that can be successfully managed with the use of other WIC supplemental foods.
- **Items not provided by WIC per Federal Regulations:**
 - Any apparatus or devices (e.g., enteral feeding tubes, bags, pumps) designed to administer WIC formulas
 - Thickening agents
 - Flavor packets
 - Medicines or drugs
 - Parenteral or intravenous nutrition products
 - Enzymes
 - Oral rehydration fluids or electrolyte solutions (e.g., Pedialyte)
 - Sport or breakfast drinks
 - Over-the-counter weight control/loss products
- **Tailoring:**
 - CPAs should tailor the food package to provide only the types and amounts of medical formula and supplemental foods most appropriate for the participant based on Health Care Provider’s documentation and CPA assessment.
 - The maximum amount should not *automatically* be provided. Do not provide foods the participant will not consume or refuses. Examples include:
 - Food allergy to a WIC food item
 - Exclusive tube feeding
 - If a WIC participant is receiving medical food or exempt infant formula from Medical Assistance (MA) or another source, and is not receiving the full amount needed as prescribed by the Health Care Provider, WIC may provide:
 - The difference up to the maximum, but may not exceed the maximum.
 - Supplemental foods as documented by Health Care Provider.
- **High Risk:**
 - All participants who receive this food package are “high risk” and require an Individual Nutrition Care Plan (INCP). INCP follow-up must be provided at least once during the certification to evaluate the appropriateness of the type and amount of formula and complementary/supplemental food. Refer to [Section 6.6, High Risk Individual Nutrition Care Plans](#) for additional information.

- Due to the nature of health conditions of WIC participants who are issued medical formula and supplemental foods that require medical documentation, the participant's Health Care Provider must provide medical oversight and instruction.
- CPAs must ensure that participants are receiving medical supervision over the prescribed medical formulas/foods.

Guidance:

- **Appropriate Follow-Up and Consultation with Medical Provider:**
 - **CPAs need to work with the Health Care Provider to assure the most appropriate food package is provided.** If a CPA questions the appropriateness of a prescribed formula/food, she should contact the Health Care Provider to discuss their findings and share any pertinent information gathered at WIC.
 - For example, if a child has been on a medical formula for some time (e.g., 6 months) and the CPA thinks the formula may be contributing to excessive weight gain, she/he should contact the physician to discuss:
 - Why the formula was prescribed;
 - How long the child should be on the formula; and
 - The plan for the child to progress to eating regular foods.
- **Complementary/Supplemental Foods:**
 - When appropriate, the use of conventional foods is important due to the additional nutrients, fiber, and other benefits that conventional foods provide.
 - WIC nutrition education should support the importance of obtaining nutrients from foods when appropriate and that a balanced diet remains the preferred overall source of nutrients.
 - Child participants who have developmental delays or swallowing disorders may benefit from receiving infant cereal in lieu of adult cereal.
 - If the Health Care Provider indicates that both formula and milk/cheese are appropriate for a child or woman participant, the CPA should tailor formula and milk/cheese to appropriate quantities.
- **Obtaining exempt infant formula and medical foods:**
 - It is important that WIC participants be able to obtain their prescribed formula in a timely manner without difficulties or additional stress.
 - Formulas such as Nutramigen, Alimentum, Similac Neosure, and Enfamil Enfacare are often available at retail stores.
 - For formulas that are not available, the local agency has two options:
 - Help locate the formula at a nearby pharmacy and determine that it will be available on a regular basis for the participant.
 - Order through the state WIC office, using the [*Special/Medical Infant Formula Order Form*](#).

- **Transitional premature formulas**, e.g. Similac Neosure and Enfacare LIPIL, may be appropriate for infants born premature until up to 9-12 months Corrected Gestational Age.
 - These formulas provide a slightly increased calorie level (22 calories/ounce) and increased amounts of calcium and phosphorous to promote adequate bone mineralization in premature infants.

- **Pediatric Formulas and Drink Mixes:** CPAs must assure there is a **medical diagnosis** for pediatric formulas and drink mixes in order to approve issuance. (Pediatric formulas and drink mixes include, but are not limited to the following products: *PediaSure*, *Boost Kids Essentials*, *Nutren Jr*, and *Bright Beginnings Pediatric Drink*.
 - **Some justifiable uses:** These products *may be appropriate* for oral motor feeding disorders; tube feedings; failure-to-thrive from an underlying medical condition; or medical conditions that increase calorie requirements beyond what is expected for the child’s age. Some conditions associated with increased caloric need include cystic fibrosis, cancer, and congenital heart disease.

 - **Failure-to-thrive (FTT):** FTT is a complex condition of diverse origins and must be diagnosed by a physician. Generally the diagnosis takes into account growth over time, development, dietary status, and psychosocial factors. Some of the indicators a physician might use to diagnose FTT include:
 - Weight consistently below the 3rd percentile for age (some use 5th percentile);
 - Weight < 80% of ideal weight for height/age;
 - Progressive fall-off in weight to below the 3rd percentile; or
 - Decrease in expected rate of growth along the child’s previously defined growth curve irrespective of its relationship to the 3rd percentile.

 - **“Picky Eaters”:**
 - When a parent/caregiver requests a pediatric formula or drink mix because the child is a “picky eater”, or “just to be on the safe side”, the CPA should deny the request and explore the child’s “picky eating” through an assessment of the family’s feeding practices and the child’s intake. For example:
 - review child’s growth (using the growth chart) and if appropriate assure parents the child is growing adequately;
 - assess food availability in the household;
 - assess family meal patterns: are there regular meals?; does the child eat alone?; does child/family watch TV during meals?
 - assess snacking: are snacks scheduled?; is snacking excessive?
 - assess child’s intake: does the child consume excessive amounts of milk? Or juice, Koolaid, or other sweet beverages?
 - assess if child is taking a bottle
 - assess for problems in the family
 - Following the assessment, the CPA can focus counseling on the specific factors possibly contributing to the problem and assist the caregiver in establishing healthier eating patterns. If appropriate, the CPA can suggest other foods for increasing the child’s caloric intake.

- Providing these products in such cases doesn't address the underlying issues, and may reinforce poor eating habits. For example, a "picky eater" who drinks several cans/day of a pediatric drink will likely have little appetite or interest in regular foods. Furthermore, it may contribute to excessive caloric intake and lead to childhood overweight.
 - Another option in some cases is to provide a regular child's food package and suggest the family purchase a product like Carnation Instant Breakfast on their own.
Compare:
 - 8 oz. can of *PediaSure* → 237 kcal, 7 g protein.
 - 8 oz. 1% milk w/ 1 pkt. *Carnation Instant Breakfast* → 240 kcal, 13 g protein
 - 8 oz. 1% milk → 110 kcal, 8 g protein.
- **Product information:** Specific product information is available in the [Minnesota WIC Formula Resource Manual](#)
 - **Letters to medical professionals:** Letters communicating approval or denial of medically-prescribed formula are included in
 - Exhibit 7-F, [Sample Approval Letter](#);
 - Exhibit 7-G, [Sample Denial Letter](#); and
 - Exhibit 7-H, [Sample Letter Denying PediaSure](#).
 - **High Risk Manual:** Refer to the *High Risk Counseling Guide* for more information on Medically-Prescribed Formulas.

See table on next page.

Food Package 3 Infants Maximum Amounts / Month										
WIC Category		Infants Mostly-BF					Infants Some-BF / Fully Formula Fed			
Food Package		Food Package 3			Food Package 3 <u>With Infant Foods</u>	Food Package 3 <u>No Infant Foods</u>	Food Package 3	Food Package 3 <u>With Infant Foods</u>	Food Package 3 <u>No Infant Foods</u>	
Mom's Food Package		5			5	5	6	**	**	
Age		0-1 mo	1-3 mo	4-5 mo	6-11 mo	6-11 mo	0-3 mo	4-5 mo	6-11 mo	6-11 mo
Exempt Infant Formula	Reconstituted Powder Ounces	104	435	522	384	522	870	960	696	960
	Reconstituted Concentrate Ounces	104	364	442	312	442	806	884	624	884
	Ready-to-Use* Ounces	104	384	448	320	448	832	896	640	896
Complementary Foods	Infant Fruits and Vegetables	N/A	N/A	N/A	128 oz.	NA	NA	NA	128 oz.	NA
	Infant Cereal	N/A	N/A	N/A	24 oz.	NA	NA	NA	24 oz.	NA

* Ready-to-Use may be issued in specific situations only. See [Section 7.5.2](#).

** A Breastfeeding Woman, whose infant is 6-11 months old and categorized "Some Breastfeeding", will not get a food package. She can remain on the program as a breastfeeding woman, but her benefits will include breastfeeding support, nutrition education, and she may receive a breastpump as appropriate.

Food Package 3 Children / Women Maximum Amounts / Month				
	Children 1-4 Years of Age	Fully Breastfeeding Women up to 1 Year Postpartum	Pregnant & Mostly- Breastfeeding Women up to 1 Year Postpartum	Some-Breastfeeding & Non-Breastfeeding Women up to 6 Months Postpartum
Reconstituted Concentrate Formula *** Powder & Ready-to- Feed may be substituted at comparable nutritive value	910 oz.	910 oz.	910 oz.	910 oz.
Supplemental Foods may be Provided <u>with Medical Documentation</u>	Any types & amounts of foods from Food Package 4	Any types & amounts of foods from Food Package 7	Any types & amounts of foods from Food Package 5	Any types & amounts of foods from Food Package 6