

# Section 7.9: Food Package for Infants, Women, and Children with Qualifying Medical Conditions (Food Package 3)

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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. 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 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 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 both infants receiving exempt (medical) formula and those receiving standard contract formula.
    - Medical documentation, including the reason why the infant cannot eat solid foods (e.g., prematurity, tube feeding), must be obtained from the health care provider prior to increasing the formula amount.

#### Children 1-4 years of age:

- Issue the food package as indicated in the tables below. The Formula Amounts Guide for Medical Formula and the 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.
- 32 4 oz. jars (128 oz.) of infant pureed fruits/vegetables may be substituted for the \$8.00 fruit/vegetable food benefit for children with qualifying medical conditions that would benefit from pureed food. Medical documentation is required.

#### Women:

- Issue the food package as indicated in the tables below. The <u>Formula Amounts Guide</u> 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 <u>Section 6.6: High Risk Individual Nutrition Care</u> Plans for additional information.

# **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 his/her 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
    - 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/yogurt are appropriate for a child or woman participant, the CPA should tailor the formula and the milk/cheese/yogurt 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 Medical Formula Order Form.

Transitional premature formulas, e.g. Similac Neosure and Enfamil Enfacare 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</li>
- Progressive fall-off in weight to below the 3rd percentile
- 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, assess:
  - Child's growth (using the growth chart) and if appropriate assure parents the child is growing adequately
  - Food availability in the household
  - Family meal patterns: Are there regular meals? Does the child eat alone? Does child/family watch TV during meals?
  - Snacking: Are snacks scheduled? Is snacking excessive?
  - Child's intake: Does the child consume excessive amounts of milk? Or juice, Koolaid, or other sweet beverages?
  - If child is taking a bottle
  - 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 Formulary and Medical Reasons for Issuance.

Letters to medical professionals: Letters communicating approval or denial of medically-prescribed formula are included in:

- Exhibit 7-F: <u>Sample Approval Letter</u>
- Exhibit 7-G: <u>Sample Denial Letter</u>
- Exhibit 7-H: Sample Letter Denying PediaSure

High Risk Manual: Refer to the *High Risk Counseling Guide* for more information on Medically-Prescribed Formulas.

### Children and Women (Maximum Amounts/Month)- Food Package 3

WIC Category	Children 1-4 years of Age	Fully Breastfeeding Women up to 1 Year Postpartum	Pregnant and Mostly- Breastfeeding Women up to 1 Year Postpartum	Some- Breastfeeding and Non- Breastfeeding Women up to 6
Reconstituted Concentrate Formula (Powder and Ready-to Feed may be substituted at comparable nutritive value)	910 oz	910 oz	910 oz	910 oz
Supplemental Foods may be provided with Medical Documentation	Any types and amounts of foods from Food Package 4*	Any types and amounts of foods from Food Package 7	Any types and amounts of foods from Food Package 5	Any types and amounts of foods from Food Package 6

<sup>\*</sup>Infant cereal (32 oz.) and pureed fruits/vegetables (128 oz.) may be provided in place of regular cereal and fruits/vegetables to medically fragile children who would benefit from pureed foods.

See next page for tables on infants receiving Food Package 3.

# Mostly-Breastfed Infants (Maximum Amounts/Month)- Food Package 3

Age	0-1 month	1-3 Months	4-5 Months	6-11 Months with Infant Foods**	6-11 Months No Infant Foods
Reconstituted Powder Formula Ounces	104	435	522	384**	522
Reconstituted Concentrated Formula Ounces	104	364	442	312**	442
Ready-to-Use* Formula Ounces	104	384	448	320**	448
Mom's Food Package	5	5	5	5	5

<sup>\*</sup>Ready-to-use may be issued in specific situations only. See <u>Section 7.5.2.</u>

See next page for table on some-breastfed and fully formula fed infants receiving Food Package 3

<sup>\*\*</sup>Infants 6-11 with healthcare provider's approval can be issued complementary foods, up to 128 oz of Infant Fruits and Vegetables and 24 oz of Infant Cereal.

# Some-Breastfed and Fully Formula Fed Infants (Maximum Amounts/Month) – Food Package 3

Age	0-3 months	4-5 Months	6-11 Months with Infant Foods**	6-11 Months No Infant Foods
Reconstituted Powder Formula Ounces	870	960	696**	960
Reconstituted Concentrated Formula Ounces	806	884	624**	884
Ready-to-Use* Formula Ounces	832	896	640**	896
Mom's Food Package	6	6	***	***

<sup>\*</sup>Ready-to-use may be issued in specific situations only. See <u>Section 7.5.2.</u>

# **Reference – Complete Listing of Hyperlinks**

#### Section 7.6: Medical Documentation

(https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/chsctns/ch7/sct n7 6.pdf)

#### Exhibit 7-D: Medical Documentation form

(https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/exhbts/ex7/7d.pdf)

#### Formula Amounts Guide

(https://www.health.state.mn.us/docs/people/wic/localagency/nutrition/formula/medical.pdf)

#### Section 6.6: High Risk Individual Nutrition Care Plans

(https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/chsctns/ch6/sct n6 6.pdf)

Medical Formula Order Form (https://survey.vovici.com/se/56206EE346B198E1)

<sup>\*\*</sup>Infants 6-11 with healthcare providers approval can be issued complementary foods, up to 128 oz of Infant Fruits and Vegetables and 24 oz of Infant Cereal.

<sup>\*\*\*</sup>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.

#### Minnesota WIC Formulary and Medical Reasons for Issuance

(https://www.health.state.mn.us/docs/people/wic/localagency/nutrition/formula/formulary.pdf)

#### Sample Approval Letter

(https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/exhbts/ex7/7f.pdf)

#### Sample Denial Letter

(https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/exhbts/ex7/7g.pdf)

#### Sample Letter Denying PediaSure

(https://www.health.state.mn.us/docs/people/wic/localagency/program/mom/exhbts/ex7/7h.pdf)

#### Section 7.5: WIC Formulas

(https:/www.health.state.mn.us/docs/people/wic/localagency/program/mom/chsctns/ch7/sct n7 5.pdf)

Minnesota Department of Health - WIC Program 625 Robert St N, PO BOX 64975, ST PAUL MN 55164-0975; 1-800-657-3942, <a href="mailto:health.wic@state.mn.us">health.wic@state.mn.us</a>, <a href="mailto:www.health.state.mn.us">www.health.state.mn.us</a>. To obtain this information in a different format, call: 1-800-657-3942

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