

## POLICY MANUAL

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### 5. NUTRITION AND BREASTFEEDING SERVICES.

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#### 5.10 Exempt Infant Formula and WIC-Eligible Nutritionals

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##### A. POLICY OVERVIEW:

Pennsylvania Women, Infants and Children (PA WIC) must issue infant formula, exempt infant formula or WIC-eligible Nutritionals to woman, infant or child participants with a documented qualifying condition.

##### B. DEFINITIONS:

Exempt Infant Formula: As defined by Section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(h)), an exempt infant formula is “[a]ny infant formula which is represented and labeled for use by an infant—(A) who has an inborn error of metabolism or a low birth weight, or (B) who otherwise has an unusual medical or dietary problem[.]” 21 USC 350a(h)(1)(A)-(B).

Phenylketonuria (PKU): Persons with phenylketonuria (PKU) cannot metabolize the amino acid phenylalanine. Such individuals must restrict dietary protein to prevent toxic accumulation of phenylalanine that can cause intellectual and developmental disabilities and neurological problems. Participants with PKU require formulas that are free of phenylalanine. Participants with PKU receive medical care, diet prescription and nutritional counseling at one of the following state contracted PKU Treatment Centers (PTCs) in Pennsylvania: Children’s Hospital of Philadelphia, St. Christopher’s Hospital for Children in Philadelphia, Children’s Hospital of Pittsburgh, Geisinger Medical Center, or Hershey Medical Center. Follow-up care is provided by community health nurses and the metabolic dietitian at the PTCs. The PKU Treatment Centers refer potentially eligible PKU patients to the PA WIC Program.

WIC-Eligible Nutritionals (WEN): “certain enteral products that are specifically formulated and commercially manufactured (as opposed to a naturally occurring foodstuff used in its natural state) 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)).

##### C. POLICY:

1. Appointments for participants requiring exempt infant formulas or WIC-eligible nutritionals in Food Package III must only be completed by a Competent Professional Authority (CPA). If a CPA is not in the clinic, other WIC staff must arrange for a CPA at a different site, the Local Agency (LA) Nutrition Education Coordinator, or State Agency (SA) nutritionist to complete the appointment. Document the consultation in the Management Information System (MIS). Refer to SA guidance for issuance of exempt infant formulas or WEN.
2. Obtain medical documentation before issuing exempt infant formula or WEN. Medical documentation must be submitted on the Pennsylvania WIC Formula Authorization Form (FAF) or may be accepted when submitted on healthcare professional letterhead or prescription form. Medical documentation must be complete regardless of the form it’s submitted in. Medical documentation is considered complete when it includes all of the following information:

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- a. Name and Birth Date of the participant receiving formula(s)
  - b. Name(s) and quantity(ies) of formula(s) being authorized for WIC issuance
  - c. Medical condition and/or ICD-10 code that justifies need for the formula(s) being authorized
  - d. Amount of formula(s) and length of use
  - e. Any special instructions related to the preparation, and/or feeding frequency of the formula(s), if applicable
  - f. Healthcare professional signature
  - g. Medical office name and contact information
  - h. Date medical documentation was completed/sent to WIC
  - i. WIC foods restrictions and length of restriction (for infants 6 months of age and older, children, and women)
3. The amount of formula specified on the medical documentation must be used to determine the quantity of formula provided to the WIC participant. However, the amount provided cannot exceed the maximum monthly amount allowed by the Federal WIC Regulations. Refer to SA guidance on maximum monthly amounts allowed.
  4. Medical documentation for exempt infant formula or WEN must be renewed every 6 months or more often based on the frequency listed on the medical documentation; with the exception of premature (pre-discharge) formulas and RTF formulas packaged in 2oz. bottles, which must be renewed on a monthly basis.
  5. Participants eligible to receive exempt infant formula or WEN must have one or more medical conditions, as determined by a healthcare professional licensed to order patient diets under Pennsylvania State law.
    - a. Healthcare professionals who are licensed to order patient diets under Pennsylvania state law are Physicians, Certified Registered Nurse Practitioners (CRNP), Physician's Assistants (PA), and Certified Nurse Midwives (CNM). Licensed Dietitian-Nutritionists (LDN) employed in the clinical setting may also authorize exempt infant formulas and WEN within their scope of practice.
      - i. It is the responsibility of the signing LDN to ensure they remain within their scope of practice to authorize products for WIC participants.
    - b. Any participant presenting medical documentation requesting exempt infant formula or WEN solely for the purpose of enhancing nutrient intake or managing body weight without an underlying medical condition will not be able to receive exempt infant formula or WEN from WIC. Food Package III is not authorized for women, infants or children whose only condition is food allergy or intolerance which does not require the use of an exempt infant formula or WEN but can be managed with one of the other WIC food packages.
  6. Exempt infant formulas or WEN may be provided to women, infants and children when medical documentation indicates that the participant has a medical condition that precludes or restricts the use of conventional foods or standard formulas. These products

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must be provided to participants in accordance with Food Package III for women, infants, and children with special dietary needs.

7. Formula may be provided for oral use or for administration via an enteral tube feeding (i.e. nasogastric tube, gastrostomy, or jejunostomy tube). Formulas administered parenterally (via peripheral or central venous catheter) are not allowed.
8. Formula must normally be provided as concentrated liquid or powder. Refer to Policy 5.08 Infant Formula, for issuing Ready-To-Feed formula.
9. Formulas may be issued individually or in combination with another formula according to the medical documentation received to best accommodate the participant's nutritional needs. However, the combined total quantity of these products issued monthly may not exceed the regulatory maximum monthly allowance.
  - a. To provide a combination of two or more formulas, refer to the medical documentation for amounts of each formula being requested, including the contract brand, if applicable. If amounts are not specified, contact the healthcare provider.
10. Medical documentation may be faxed or provided electronically to the LA or clinic. Verbal orders from the healthcare professional for exempt infant formulas and WEN can be accepted by a CPA on a case-by-case basis. Verbal orders must be clearly documented in the MIS including the date, name of healthcare professional providing verbal order, product and amount. Written confirmation of the medical documentation must be obtained within one month after the phone call and before providing additional benefits.
11. If a healthcare professional prescribes a formula which is not on the WIC-approved formula list, LA staff must contact the SA.
  - a. The medical documentation may be requested by the SA.
  - b. SA staff will review documentation of relevant assessment of formula preparation and infant feeding. If needed, SA may request a completed Bottle Feeding Checklist.
  - c. After reviewing the information, the SA may approve the formula for the specific participant by adding the product to the MIS, and LA WIC staff will be notified when the new product is available for ordering. It may take 24-48 hours before the LA staff will be able to order the formula through the warehouse or the participant may purchase at a WIC-authorized vendor-retailer store.
12. Refer to Policy 4.03, Special Formula Distribution Center, for information on ordering and delivering exempt infant formulas and WENs from the Special Formula Distribution Center (SFDC).
13. Exempt formulas and WEN must not be provided to participants while they are hospitalized, incarcerated, or institutionalized.

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##### 14. PKU Formula Issuance:

- a. When PKU formula is required, it will not be issued by WIC. PKU formula will be covered by the participant's insurance or medical assistance. However, Food Package III and the PKU formula the participant is on must be selected when creating the participant's food package in the MIS.
- b. WIC will issue any non-PKU formula that is authorized. The total amount of all formula (non-PKU and PKU) must not exceed the USDA allowable maximum.
- c. Medical Nutrition Therapy (MNT) is provided by a metabolic dietitian at a PKU Treatment Center. WIC nutrition education contacts are still required for appropriate topics such as, but not limited to, breastfeeding support, physical activity, and shopping on a budget.
- d. In the case that the SA receives referral information, the SA nutritionist will contact the LA.
- e. The LA will contact the patient referred to WIC for PKU formula to schedule a WIC appointment.
- f. All endorsers and/or proxies of PKU participants must come to WIC at least tri-monthly for nutrition education contacts and issuance of allowed foods and/or standard infant formula. Endorsers must be seen by a CPA at each visit.

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#### Reference(s):

1. WIC Regulation: 7 CFR 246.10
2. U.S. Department of Agriculture, Food and Nutrition Service, Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), WIC Food Packages - Regulatory Requirements for WIC-Eligible Foods, <https://www.fns.usda.gov/wic/wic-food-packages-regulatory-requirements-wic-eligible-foods#WIC-ELIGIBLE%20NUTRITIONAL> (page last updated November 3, 2023)

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#### Policy Status:

1. This Policy supersedes Policy Number 7.08, dated August 13, 2018.