

4.09 Food Package III, Women, Infants and Children with Qualifying Medical Conditions

POLICY:

Food Package III 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 nutritional) because the use of conventional foods is precluded, restricted, or inadequate to address their special nutritional needs.

DEFINITIONS:

Exempt Infant Formulas: Exempt infant formulas include formulas for infants with an inborn error of metabolism, low birth weight, or an unusual medical or dietary condition. Exempt infant formulas are primarily formulated for infants less than 1 year old.

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 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 (21U.S.C. 360ee(b)(3)).

Out-of-Date Formula: Formula is considered out-of-date on the first day of the month labeled as the expiration date.

PROCEDURE:

A. Qualifying Conditions

1. Participants who are eligible to receive Food Package III must have one or more qualifying conditions, as determined by a health care professional licensed to write medical prescriptions under State Law.
2. The qualifying conditions include but are not limited to:
 - a. Premature birth
 - b. Low birth weight
 - c. Failure to Thrive
 - d. Inborn errors of metabolism and metabolic disorders
 - e. Gastrointestinal disorders
 - f. Malabsorption syndromes
 - g. Immune system disorders
 - h. Severe food allergies that require an elemental formula
 - i. Life threatening disorders, diseases and medical conditions that impair ingestion, digestion, absorption, or the utilization of nutrients that could adversely affect the participant's nutrition status.
3. Food Package III may not be issued solely for the purpose of enhancing nutrient intake or managing body weight.

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B. Non-Authorized Issuance of Food Package III

1. This food package is not authorized for:
 - a. **Infants** whose only condition is:
 - i. 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; or
 - ii. A non-specific formula or food intolerance.
 - b. **Women** and **Children** who have a food intolerance to lactose or milk protein that can be successfully managed with the use of one of the other WIC food packages (i.e. Food Package IV-VII).
 - c. Any participant solely for the purpose of enhancing nutrient intake or managing body weight without an underlying qualifying condition.

C. Restrictions on Issuance of WIC Formulas in Ready-to-Feed (RTF) Forms

1. WIC formulas (infant formula, exempt infant formula and WIC-eligible nutritionals) must be issued in concentrated liquid or powder physical forms unless the requirement for issuing ready-to-feed are met (see **Policy 4.03 Ready-to-Feed Formula**).
2. In addition to those requirements, there are two additional conditions which may be used to issue ready-to-feed formulas in Food Package III:
 - a. If a ready-to-feed form better accommodates the participant's condition;
or
 - b. If it improves the participant's compliance in consuming the prescribed WIC formula.

D. Unauthorized WIC Costs

1. All apparatuses or devices (i.e. enteral feeding tubes, bags and pumps) designed to administer WIC formulas are not allowable WIC costs.
2. If a participant requires hospitalization, WIC will not provide WIC formulas during the time period the participant is a hospitalized patient.

E. Authorized Categories of Supplemental Foods

1. The supplemental foods authorized in the food package require medical documentation for issuance and include:
 - a. WIC formula (infant formula, exempt formula and WIC-eligible nutritionals)

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- b. Infant cereal
- c. Infant foods
- d. Milk
- e. Cheese
- f. Yogurt
- g. Eggs
- h. Canned fish
- i. Fresh fruits and/or vegetables
- j. Breakfast cereal
- k. Whole wheat/whole grain bread and other whole grains
- l. Juice
- m. Legumes and/or peanut butter

F. Required Medical Documentation (Prescription Formula Form WIC-53)

1. A **Prescription Formula Form (WIC-53)** is required for the issuance of the following supplemental foods:
 - a. An infant formula that is prescribed to a child or woman
 - b. An exempt infant formula, prescribed to any participant
 - c. A WIC-eligible nutritional, prescribed to any participant
 - d. Any authorized supplemental foods, prescribed to any participant receiving Food Package III
2. A **Prescription Formula Form (WIC-53)** must be completed by a healthcare professional licensed to write medical prescriptions under State Law.
3. The **Prescription Formula Form (WIC-53)** must include:
 - a. The participant's full name and birth date
 - b. Parent/Guardian's full name
 - c. The WIC formula, (infant formula, exempt infant formula or WIC-eligible nutritional) prescribed and form
 - d. The amount of prescribed WIC formula needed per day
 - e. The authorized supplemental food(s) appropriate for the qualifying condition(s) and their prescribed amounts
 - f. Length of time the prescribed WIC formula and/or supplemental food is required by the participants, up to six (6) months
 - g. The qualifying condition(s) for issuance of authorized supplemental food(s) requiring medical documentation
 - h. The printed name, signature, including electronic signature, date, and contact information of the prescribing healthcare provider

Note: The **Prescription Formula Form (WIC-53)** must be completed. Any missing information will make the WIC-53 incomplete and not valid. See **Attachment #2** for "Gold Standard" WIC-53 examples.

4. Completed **WIC-53** forms are accepted by hard copy, i.e. mail or via participant, or electronically, i.e. fax or email.

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- a. **WIC-53** forms are available at every WIC clinic and on the West Virginia WIC website at:
<https://dhhr.wv.gov/WIC/formsmaterials/Documents/WIC%2053%20Form%20Nov%202019.pdf>
5. Medical documentation may be provided by telephone to a Nutritionist (CPA) who must promptly document the information on the **Prescription Formula Form (WIC-53)**. The collection of the required information by telephone for medical documentation purposes may only be used until written confirmation is received from a healthcare professional licensed to write medical prescriptions and used only when absolutely necessary on an individual participant basis.
 - a. The clinic must receive the **Prescription Formula Form (WIC-53)** completed by a healthcare professional within 30 days after accepting the initial medical documentation by telephone.
6. **Prescription Formula Forms (WIC-53)** must be scanned into the participant's chart on the **Medical Documentation Screen**.
 - a. The **Medical Documentation Screen** must be completed using the information from the completed **WIC-53** form.
7. Each Local Agency Director or Nutrition Coordinator will complete a monthly review of 10% of participant records who are prescribed Food Package III to ensure the **Prescription Formula Forms (WIC-53)** are completed.
 - a. The Local Agency will be responsible for documenting their review on **Attachment #1** and submitting it to the WIC Program Specialist by the 15th of the following month.

G. Medical Supervision Requirement

1. Due to the nature of the health conditions of participants who are issued supplemental foods that require medical documentation, close medical supervision is essential for each participant's dietary management. The responsibility remains with the participant's health care provider for this medical oversight and instruction. This responsibility cannot be assumed by personnel at the WIC State or Local Agency. However, it would be the responsibility of the WIC Nutritionist (CPA) to ensure that only the amounts prescribed by the participant's health care provider are issued in the participant's food package.

H. Nutritional Assessment for Formula Change

1. When a participant requests an exempt formula or WIC-eligible nutritional, a **Formula Prescription Form (WIC-53)** must be completed by a healthcare professional licensed to write medical prescriptions under State Law.
2. The participant will receive a complete nutrition assessment from a Nutritionist (CPA). The assessment will include but is not limited to:

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- a. Has the infant recently been sick or had a fever?
- b. Has the infant been taking a medication?
- c. Is the formula being properly diluted?
- d. Is the formula being adequately refrigerated?
- e. Is the formula being prepared in a sanitary manner?
- f. Is the water supply safe?
- g. Is the infant fed formula left over from a previous feeding?
- h. Were new foods recently introduced?
- i. Is there a family history of cow's milk allergy or intolerance?
- j. Has the family experienced any emotional stress?
- k. Is the infant positioned correctly for feeding?
- l. Is the infant being overfed?
- m. Is the infant being burped at necessary intervals?
- n. Has there been a change in the infant's stool composition or frequency?
- o. Has the infant been introduced to any other formulas other than the one currently prescribed?
- p. Has the infant recently been eating more or less?

I. Metabolic Formula

1. Metabolic Formula may be provided to WIC participants in coordination with the Office of Maternal, Child and Family Health (OMCFH) and a Metabolic Specialist. If the prescribed metabolic formula is available, it will be ordered through CAP warehouse.
2. When a client accesses WIC prior to seeing a Metabolic Specialist:
 - a. The WIC Nutritionist (CPA) will advise the client to contact Newborn Screening at 1-800-642-9704 regarding the formula.
 - b. No formula or food will be issued.
 - c. A referral will be made to the WV University Genetics Team.

Medical Geneticist:
Dr. TaraChandra Narumanchi
WVU Health Sciences Center
PO Box 9214
Morgantown, WV 26506
304-598-4835

3. The WIC clinic will send a **Prescription Formula Form (WIC-53)** to the Metabolic Specialist upon expiration of the current form, as the WIC participant only sees the Metabolic Specialist annually.
4. A participant who is issued a metabolic formula must complete their certification and high-risk follow-up appointments.

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5. A participant who is issued a metabolic formula must complete their WIC Nutrition Education requirements.
 - a. Education will be provided on using and spending WIC food benefits. The **West Virginia WIC-Approved Food List (WIC-09)** will be supplied to the Metabolic Specialist who will educate the client on allowed supplemental food.
 - b. No nutrition or breastfeeding education contacts will be provided unless the Metabolic Specialist consents, in writing.
 - c. Dietary guidance will not be given by the Nutritionist (CPA) during high-risk contacts and follow-up appointments for the WIC participant who is seen by a Metabolic Specialist. Education may be given on the correct use of WIC food benefits and any other topics related to the WIC Program.
 - d. The Nutritionist (CPA) will document in the **Nutrition Care Plan** that the participant is being seen by a Metabolic Specialist.

J. Religious Eating Patterns of Individuals

1. For individuals that require a special formula because of religious beliefs, contact the State WIC Office for specific guidance.

K. Damaged or Out-of-Date WIC Formula

1. Any damaged or out-of-date containers of ready-to-feed formulas in the clinic must be discarded or destroyed. *Note:* See **Policy 3.08 Returned Formula**
2. The labels from each container must be removed when discarding or destroying.

ATTACHMENTS:

1. Prescription Formula Form (WIC-53) Monitoring Documentation Form
2. "Gold Standard" Prescription Formula Form (WIC-53) Examples

REFERENCES:

1. WIC Regulations 7 CFR 246.10 Supplemental Foods
2. USDA Nutrition Services Standards, Chapter 13, Food Package Prescriptions
3. USDA Special Supplemental Nutrition Program for Women, Infants and Children, Food Package Policy and Guidance, Chapter 2, Food Package Design
4. USDA Special Supplemental Nutrition Program for Women, Infants and Children, Food Package Policy and Guidance Chapter 3, Determining Eligibility of WIC Foods
5. USDA Special Supplemental Nutrition Program for Women, Infants and Children, Food Package Policy and Guidance Chapter 4, Nutrition Tailoring of WIC Food Packages
6. USDA Special Supplemental Nutrition Program for Women, Infants and Children, Food Package Policy and Guidance Chapter 6, WIC Formula

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7. WIC Policy Memorandum 2020-1 Donation of Unused, Returned Infant Formula