

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

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**POLICY:**

The purpose of this policy is to provide information on WIC participants with a documented qualifying condition that requires issuance of WIC formula (contract infant formula, exempt infant formula or WIC-eligible nutritionals) because the use of conventional food 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 problem. 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**Out-of-Date Formula:** Formula is considered out-of date on the first day of the month labeled as the expiration date.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. Medical Diagnosis that Require Issuance of contract infant formula, exempt infant formula or WIC-eligible nutritionals**

Participants who are eligible to receive contract infant formula, exempt infant formula or medical food must have one or more qualifying conditions, as determined by a health care professional licensed to write medical prescriptions under State law. The qualifying conditions include but are not limited to the following:

1. Premature or low birth weight infant(s).
2. Low Birth Weight.
3. Failure to thrive.
4. Inborn errors of metabolism and metabolic disorders.
5. Gastrointestinal disorders.
6. Malabsorption syndromes.
7. Immune system disorders.

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

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8. Severe food allergies.
9. Diseases and medical conditions that could adversely affect the participant's nutrition status.

**B. Conditions that are Non-Qualifying Medical Diagnosis for Issuance of Contract Infant Formula, Exempt Infant Formula or WIC-Eligible Nutritionals**

1. Infants whose only qualifying condition is:
  - a. A diagnosed formula intolerance or food allergy to lactose, sucrose, milk protein or soy protein that does not require the use of exempt infant formula.
  - b. A non-specific formula or food intolerance.
2. Women and children who have food intolerance to lactose or milk protein that can be successfully managed with the use of one of the other WIC food packages.
3. Any participant solely for the purpose of enhancing nutrient intake or managing body weight without an underlying qualifying condition.

**C. Unauthorized Products Which Are NOT Authorized by WIC**

All apparatus or devices such as enteral feeding tubes, bags or pumps, designed to administer WIC formulas are not an allowable WIC cost.

**D. Other Cases in Which Special Formula is Not Provided**

1. If a participant requires hospitalization, WIC cannot provide special formula during the actual period of time in which the participant is in the hospital.

**E. Nutritional Assessment for Formula Change**

Upon request by the participant for a special formula, the Competent Professional Authority (CPA) should make an assessment based on the following questions:

1. Has the infant recently been sick or had a fever?
2. Has the infant been taking a medication?
3. Is the formula being properly diluted?
4. Is the formula being adequately refrigerated?
5. Is the formula being prepared in a sanitary manner?
6. Is the water supply safe?

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

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7. Is the infant fed formula left over from a previous feeding?
8. Were new foods recently introduced?
9. Is there a family history of cow's milk allergy?
10. Has the family experienced any emotional stress?
11. Is the infant positioned correctly for feeding?
12. Is the infant being overfed?
13. Is the infant being burped at necessary intervals?

**F. Authorized Categories of Supplemental Foods**

Each supplemental food authorized in food package III is dependent on participant category, requires medical documentation for issuance and includes the following:

1. Contract Infant formula (for children or women)
2. Exempt infant formula
3. WIC-eligible nutritionals
4. Infant cereal
5. Infant food fruits and vegetables
6. Milk or soy milk
7. Cheese
8. Eggs
9. Canned fish
10. Authorized fruits and vegetables
11. Breakfast cereal
12. Whole grains
13. Juice
14. Legumes and/or peanut butter

**G. Required Medical Documentation**

1. Medical documentation is required for issuance of the following supplemental foods:
  - a. Any infant formula prescribed to a child or adult who receives food package III.
  - b. Any exempt infant formula
  - c. Any WIC-eligible nutritionals
  - d. Any authorized supplemental food issued to participants who receive food package III
2. When a health care professional licensed to write medical prescriptions under State law has made a medical determination that the participant has a qualifying condition, documentation of the health care professional's determination will be

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

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included in the participant's record and scanned into Crossroads on the Attach Medical Documentation screen.

3. The participant will be given a copy of the **Prescription Formula Documentation Form (WIC-53)** to be completed and signed by a health care professional to write medical prescriptions under State law.
  - a. The completed form must include:
    - The name of the authorized WIC formula (contract infant formula, exempt infant formula, WIC-eligible nutritionals) prescribed
    - The amount of contract infant formula, exempt infant formula or WIC-eligible nutritionals needed per day
    - The authorized supplemental food(s) appropriate for the qualifying condition(s) and their prescribed amounts
    - Length of time the prescribed WIC formula and/or supplemental food is required by the participant
    - The qualifying condition(s) for issuance of the authorized supplemental food(s)
    - Signature, date and contact information
    - The participant name
  - b. The completed form may be returned to the participant to take to the WIC clinic, or faxed directly to the WIC clinic.
4. Special formulas including premature infant formula will be issued for the period documented by the physician or healthcare provider with prescriptive authority, but not to exceed six (6) months.
  - a. When it is not administratively feasible to obtain written documentation, special formula may be issued for **only** one (1) month when a phone contact by the WIC CPA with the health care professional, with prescriptive authority, is documented on the **Prescription Formula Documentation Form (WIC-53)**.
5. Once the **Prescription Formula Documentation Form (WIC-53)** is properly filled out, and signed and dated by the CPA, they will then assign the proper food package and scan the signed WIC-53 into the Attach Medical Documentation screen. Formula may be given in powdered or concentrated form. Ready-to-feed formula may only be given according to policy 4.03, **Ready-to-Feed Infant Formula**.
6. The qualifying medical diagnosis written on the Prescription Formula Documentation Form (WIC-53) must match the qualifying medical diagnosis

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

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selected in the medical reason drop down located on the Attach Medical Documentation screen.

**H. Medical Documentation Supervision Requirement**

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 CPA to ensure that only the amounts of supplemental foods prescribed by the participant's health care provider are issued in the participant's food package.

**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 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 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. MaryBeth Hummel  
WVU Health Sciences Center  
PO Box 9214  
Morgantown, WV 26506  
304-293-7332 or  
1-800-WVA-MARS

3. The WIC clinic is responsible for mailing a new **Prescription Formula Documentation Form (WIC-53)** to the Metabolic Specialist upon expiration of the current form, as the WIC participant only sees the Metabolic Specialist annually.

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

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4. Nutrition Education provided by WIC to a participant issued Metabolic Formula
  - a. Education will be provided on the correct use of the WIC food benefits. The **West Virginia WIC-Approved Food List (FD-09)** will be supplied to the Metabolic Specialist who will educate the client on allowed supplemental food.
  - b. No nutrition or breastfeeding education (including both individual and group nutrition education contacts) will be provided unless the Metabolic Specialist consents, in writing.
5. High Risk Contact and Follow-up Visits Provided by WIC
  - a. Dietary guidance will not be given by the CPA during high risk contacts and follow-up visits 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.
  - b. The CPA will record in the **participant's Care Plan** during the certification visit, in which a high risk nutrition risk code is assigned to the WIC participant, that they are being seen by a Metabolic Specialist.

**I. Religious Eating Patterns of Individuals**

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

**J. Damaged or Out-of-Date Special Formula**

Labels on all cans of damaged or out-of-date formula in the clinic should be removed and destroyed. After the labels have been removed and destroyed, the cans should then be discarded/destroyed.

**REFERENCES:**

1. WIC Regulations 246.10, Supplemental Foods
2. FNS-268, Infant Formulas, Exempt Infant Formulas, and Medical Foods Eligible for use in WIC