

	<b>N.Y.S. DEPARTMENT OF HEALTH – WIC PROGRAM MANUAL</b>		
	<b>Subject: Food Package III Participants with Qualifying Medical Conditions</b>	<b>Section # 1255</b>	
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**POLICY**

1. *Food Package III provides medically fragile:*
  - *Infants with exempt infant formula*
  - *Infants 6 months or older with higher amounts of contract infant formula in lieu of infant solid foods*
  - *Children with contract formula, exempt formula and/or WIC-eligible nutritionals*
  - *Women with formula and/or WIC-eligible nutritionals*
  
2. *A health care provider licensed to write medical prescriptions (physician, physician’s assistant, nurse practitioner or midwife with prescriptive privileges) must document that the participant has at least one qualifying medical condition and requires a Food Package III WIC formula and/or WIC-eligible nutritionals.*
  
3. *Food Package III recipients are eligible to receive all of the supplemental foods for which they would have qualified in the absence of their special medical needs. The local agency competent professional authority must tailor the food package to provide the type and amount of foods most appropriate for the participant based on professional judgment, assessed need, and the health care provider’s medical documentation.*
  
4. *Medically fragile infants 6 months or older, unable to consume infant solid foods are eligible to receive additional contract formula, exempt infant formula or WIC-eligible nutritionals with medical documentation. This issuance equals the maximum monthly allowance for infants ages 4 through 5 months of the same feeding option/breastfeeding status.*
  
5. *The competent professional authority must notify the participant’s health care provider and request clarification if the Food Package III request is unclear, questionable, or appears inappropriate for clarification/resolution. Medical documentation for inappropriate formula requests must be disapproved by the competent professional authority.*
  
6. *The competent professional authority must restrict the issuance of Food Package III formula and/or WIC-eligible nutritionals based on the health care provider’s medical documentation. The amount of formula issued must not exceed the Monthly Maximums of NYS Approved Formulas.*
  
7. *The competent professional authority may authorize ready-to-use formula or WIC-eligible nutritionals for Food Package III participants when the competent professional authority determines and documents in the participant’s record that at least one of the allowable conditions for ready-to-use issuance exists.*
  
8. *All medical/health data and documentation must be maintained in the participant’s record.*

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*9. Local agency staff must educate the participant/caretaker on the proper procedure for redeeming checks for exempt formula and WIC-Eligible Nutritionals. Checks for exempt formula, WIC-Eligible Nutritionals and Special Formula Food Instruments (SFFIs) must only be redeemed at WIC authorized pharmacies and/or retail vendors with a pharmacy.*

**BACKGROUND**

Federal Regulations 7 CFR 246.10 Food Package III and Supplemental Foods.  
 This food package is reserved for medically fragile women, infants and child participants who require WIC formula (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. Medical documentation of the qualifying condition(s) and prescribed formula is required.

**DEFINITIONS**

**WIC-Eligible Nutritionals** – (formerly called WIC-Eligible Medical Food) 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.

Refer to Acronyms and Definitions.

**PROCEDURE**

1. Medical documentation is **required**:
  - For infants requiring an exempt infant formula.
  - For infants greater than 6 months of age requiring higher amounts of contract formula due to their inability to consume solid foods.
  - When issuing contract infant formula, exempt formula or WIC-eligible nutritionals to women and children.
  - Prior to issuance of foods at 6 months of age for infants receiving Food Package III formula unless the health care provider (HCP) has deferred to the WIC competent

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professional authority (CPA) via medical documentation.

- When changes to the prescribed foods and Food Package III WIC formula are needed within the medical documentation approval period, and/or at every certification.

2. Medical documentation must be obtained prior to issuance and must include:

- Participant’s name and date of birth;
- Qualifying medical condition(s);
- Name of the WIC formula(s) and/or WIC-eligible nutritional(s);
- Quantity needed (ounces) per day of prescribed WIC formula(s) and/or WIC-eligible nutritional(s);
- Length of time prescribed (approval period);
- Supplemental food restrictions/contraindications; or HCP medical documentation deferring to WIC for identifying appropriate supplemental foods, their prescribed amounts, and length of time required by the participant;
- Signature of the HCP and date; and,
- Contact information of HCP (may be stamped).

This information **must** be provided to the local agency on the New York State Department of Health’s WIC Medical Documentation Form, prescription or letter on letterhead (a faxed form, prescription or letter is acceptable). A verbal order may be accepted from the HCP; however, only one month of benefits can be issued. If the HCP is unavailable, the CPA may use professional judgment to issue one month of benefits until written documentation is obtained. Under no circumstances may a second consecutive monthly issuance of benefits be provided without appropriate written medical documentation.

3. Communication (fax, phone call, participant referral, etc.) with the HCP is required when formula omissions/discrepancies/HCP requests included in the medical documentation are not in compliance with policy or appear to be inappropriate for the participant. Follow specific state and local agency/sponsor agency requirements for obtaining participant consent for WIC to contact the HCP.

4. Food Package III is **not** authorized for:

- 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 a formula.
- 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 Packages IV-VII).
- The purpose of solely enhancing nutrient intake or managing body weight without an underlying qualifying medical condition.
- A non-specific food intolerance.

5. Ready-to-use Food Package III WIC formulas can be authorized only when the CPA

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determines and documents in the participant’s record that at least one of the following conditions exists:

- Unsanitary or restricted water supply;
  - Inadequate refrigeration;
  - Caretaker has difficulty diluting concentrated or powder formula;
  - Formula product is available only in the ready-to-use form;
  - The ready-to-use form better accommodates the participant’s condition; and/or
  - The ready-to-use form improves the participant’s compliance in consuming the prescribed WIC formula.
6. The medical/health data must be documented and updated, as needed, in the participant’s record.
  7. Local agency staff must discuss correct WIC check cashing procedures of exempt formula and WIC-Eligible Nutritionals checks with participants, educate participants where these formula checks can be cashed and include guidance in identifying appropriate vendors, as needed.

<b>GUIDANCE</b>
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Qualifying medical conditions include, but are not limited to, premature birth, low birth weight, failure to thrive, inborn errors of metabolism and metabolic disorders, gastrointestinal disorders, malabsorption syndromes, immune system disorders and severe food allergies. Life threatening disorders, diseases and medical conditions that impair ingestion, digestion, absorption or utilization of nutrients that could adversely affect the participant’s nutrition status are qualifying medical conditions.

Non-specific symptoms such as formula/food intolerance, fussiness, gas, spitting up, constipation, diarrhea, vomiting, dermatitis, colic, to enhance or manage body weight (without an underlying condition) are not qualifying medical conditions. Participant preference is not a qualifying medical condition. Low birth weight and premature birth apply only to infants and children < 24 months old; failure to thrive applies only to infants and children.

If the HCP indicates via medical documentation that the WIC CPA may identify appropriate supplemental foods, their prescribed amounts, and length of time required by the participant, the CPA uses professional judgment and conversations with parents/caretaker to determine appropriate foods. If the HCP does not indicate a referral to WIC or WIC Supplemental Foods through medical documentation, the CPA contacts the HCP for clarification.

The CPA uses professional judgment when there are omissions or discrepancies among the medical documentation provided, nutritional assessment and parent/caretaker requests. For example, the assessment reveals that the participant has a peanut allergy, but the medical

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documentation form indicates that peanut butter may be given. In this case, the CPA uses professional judgment and tailors the peanut butter out of the food package. If the HCP does not indicate the specific type of milk, the CPA, after completing an assessment, uses their professional judgment and jointly determines the appropriate milk to be issued with the parent/caretaker. Milk options include whole, 1% (low-fat) or non-fat (skim).

The CPA collaborates with the HCP when the CPA determines another formula/food is more appropriate. The CPA discusses their recommendation with the caretaker and/or HCP as needed. If the HCP disagrees with the CPA's suggestion, and the medical documentation is justified by the HCP, appropriate, and meets WIC guidelines, the CPA must provide the prescribed formula. The CPA should continue to collaborate and follow up with HCP as needed. During collaboration with the HCP, the CPA may encourage (but not require) the following as applicable:

- Allergy test to confirm diagnosis, if age appropriate;
- Trial of contract formula prior to exempt formula; and
- Transition from exempt formula to cow's milk or soy beverage at one year of age.

If there is any reason to suspect fraud, refer to the Bureau of Special Investigations (BSI).

Refer to the Monthly Maximums of NYS Approved Formulas for formula information and issuance details.

Refer to the Active Vendor List for information on contracted WIC Vendors.

Refer to WIC Program Manual sections:

- WIC Formulas
- Nutrition Support Staff and CPAs
- Food Package Prescription and Tailoring
- WIC Approved Foods and Formula
- Food Packages for Breastfeeding Participants
- Food Package Modifications for Homeless Participants
- Medical/Health Data
- Health and Nutrition Update
- Confidentiality and Releasing Information
- Reissuing Food Instruments

Refer to Policy Supplements:

- Nutrition Support Staff and CPAs Policy Supplement
- Health and Nutrition Update Policy Supplement

Refer to the Formula and Forms folders on the Common Drive for additional formula related tools for staff and participants.