### **Medical Documentation**

Policy No. NS- 210.12

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# **Policy**

Medical documentation is required prior to the issuance of any exempt infant formulas or WICeligible nutritionals. Participants who transfer from another state within a valid certification period and require a state approved exempt formula or WIC-eligible nutritional may receive one month of the product without written medical documentation.

Issuance of an exempt infant formula or WIC-eligible nutritional may be authorized when the medical documentation includes a qualifying medical condition consistent with the manufacturer's indicated use or nutritional profile of the product prescribed.

The local agency must obtain new medical documentation for continued issuance of any exempt infant formulas and WIC-eligible nutritionals at every certification or when the planned length of use documented by the medical provider expires.

New medical documentation is required when the type or amount of exempt formula or WIC-eligible nutritional changes.

Medical documentation is required for the issuance of infant formulas or WIC-eligible nutritionals to participants greater than 12 months of age. This includes the issuance of a nutritional supplement when the consumption of conventional foods is prohibited, restricted, or inadequate.

A current release of information signed by the participant must be in place prior to any conversations and or correspondence regarding the WIC participant with their prescribing medical provider(s).

Medical documentation that has been clarified by the medical provider and updated by the WIC Program staff is valid for the full certification period and used in the same manner as medical documentation not requiring clarification.

When a current release of information, signed by the participant is in place, verbal medical documentation (verbal order) may be obtained from the prescribing medical provider(s) and used to provide exempt infant formulas and WIC-eligible nutritionals for one month.

### **Purpose**

To ensure program cost incurred from the issuance of exempt infant formulas and WIC-eligible nutritionals is medically indicated, and necessary to sustain the health and wellbeing of the participant.

### **Procedures**

I. Accept the <u>Georgia WIC Request for Medical Formulas and WIC Supplemental Foods</u>
(RMF) as an original written document, an electronic document, or by facsimile.

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- A. Accept a physician's prescription pad or medical office letterhead in lieu of the Georgia WIC RMF.
- II. Do not accept the following forms for medical documentation:
  - A. Prescription forms or prescription pads which are pre-printed or pre-stamped with a formula requiring a prescription.
  - B. Forms or prescription pads containing formula advertising.
  - C. Prescription pads or forms that include a pre-printed list of formulas from which the healthcare provider is expected to choose from a list of formulas. For example, a prescription form that lists ten (10) common special formulas and one (1) blank space to list other formulas is not allowed.
- III. Verify that medical documentation received includes all required information. See the Medical Documentation Content Requirements for more details.
- IV. Use the <u>Formula Algorithm for Infants on Georgia WIC</u> and the <u>Formula Algorithm for Children on Georgia WIC</u> as a guide for authorizing the issuance of formulas based on the manufacturer's indicated use and qualifying medical conditions. When issuing nutritional supplements, reference the <u>Issuance Requirements for Nutritional Supplements</u>.
- V. Obtain clarification for missing or unclear information provided by medical documentation with either the participant, per the CPA nutrition assessment, or by the medical provider using the procedures described below.
  - A. Verify that a release of information signed by the participant is available and current prior to contacting their medical provider. (Reference Section VIII of this policy for procedures on obtaining the participant's release of information.)
  - B. Contact the medical provider for clarification/verification of any of the information listed below or to request medical documentation if it was not provided.
    - 1. New or undocumented diagnoses
    - 2. Information provided by a source unfamiliar with the information requested
    - 3. Foods that have been selected as contraindicated by the medical provider which parent/caregiver reports as being allowed

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- C. Clarify the following information based on parent/caregiver's report or per the CPA nutrition assessment:
  - 1. Formula/nutritional history
  - 2. Signs/symptoms that supports the documented diagnosis (i.e. severe allergies/allergic reactions)
  - 3. Product form, flavor, with fiber etc.
  - 4. Historical/previously documented chronic diagnoses available in the medical record or RMF
  - 5. Food restrictions such as nothing by mouth (NPO)
  - 6. Additional foods or formula to be excluded from the food package
- VI. Document clarifying information on the current medical documentation form, initial and date each change, and depending on the source of the clarification:
  - A. Record the name and credentials of the provider or other medical personnel (relaying the information on behalf of the provider) who gave the verbal clarification by each change.
  - B. Document the applicable nutrition assessment information, the date it was obtained, and the source where it may be referenced (i.e. "Patient was premature, 35 weeks gestation see RMF dated 7/28/2020).
  - C. Document the information provided by the parent/caregiver and the name and relationship of the caregiver (i.e. "unflavored verified by mother, Jane Smith, 2/25/19").
  - D. When Section 3 Authorized Supplemental Foods section is left blank, determine foods appropriate based on the CPA's nutritional assessment and/or parent/caregiver's report.
    - 1. Document foods not to be issued in the "Comments" section of the RMF or on the alternate form as appropriate.
    - 2. The CPA must sign their full name, title, and date with the authorized supplemental foods documentation.
- VII. Request new medical documentation if the authorized signature is not included on the medical documentation, is completed using a signature stamp, or if the form was signed by an unauthorized provider. Provider signatures cannot be documented as clarifying information.

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- VIII. Discuss the release of information requirements with the participant prior to them completing a release of information.
  - A. Assist the participant with completing a Release of Information, Section 5, on the Georgia WIC RMF or the DPH Authorization for Release of Protected Health Information if they wish to authorize a release of information to the provider.
    - 1. If the participant does not wish to authorize release, the CPA shall document "Declined" on the signature line and document the date the release was declined.
    - 2. If the participant refuses to sign a Release of Information, explain to them that they must contact the medical provider themselves to request new medical documentation with required clarity.
  - B. Reference the <u>Release of Information Frequently Asked Questions (FAQs) for</u> additional details.
- IX. Document the details of verbal medical documentation (verbal order) on the <u>Georgia WIC</u> <u>RMF</u> or alternate form and sign/date the information.
  - A. Record the complete name and credentials of the authorized prescribing medical provider in the place of his/her original signature.
  - B. Request written medical documentation of the verbal order from the medical provider to be received as soon as possible but no later than two weeks after the initial verbal order.
  - C. Do not accept consecutive verbal orders for the same medical documentation request.

## **Authority**

7 C.F.R. § 246.10(d)

21 C.F.R. § 107.3 (definition of infant exempt formula)

## **Definitions/Supporting Documentation**

**Competent Professional Authority (CPA)** – An individual on the local agency staff who is authorized to determine nutritional risk and prescribe supplemental foods. The following individuals may be authorized and trained to serve as a CPA: physicians, nutritionists (bachelor's or master's degree in Nutritional Sciences, Community Nutrition, Clinical Nutrition, Dietetics, Public Health Nutrition), registered dietitians, licensed dietitians, registered nurses, and physician assistants

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(certified by the National Committee on certification of Physicians Assistants or certified by the State medical certifying authority), or State or local medically trained health officials.

**Exempt Infant Formula** – An infant formula that is intended for commercial or charitable distribution that is represented and labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems.

**Nutritional Supplement** – A concentrated source of nutrients for children and adults, often in the form of a beverage, providing supplemental or complete nutrition intended for oral or tube feedings.

WIC-Eligible Nutritionals – means 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 (21 U.S.C. § 360ee(b)(3)).