Approval of Non-Contract Formula

Purpose

To ensure that infant formulas, exempt formula and WIC-eligible nutritionals requiring medical documentation are approved for appropriate medical reason in compliance with WIC regulations.

Authority

7CFR Part 246.10

Policy

Non-contract formula may be approved for valid medical conditions when the use of WIC contract formula is contraindicated.

Definitions

Formula – the term “formula” used throughout this policy refers to all contract and non-contract formulas, including milk and soy-based, low-lactose formulas, nutritional beverages, additives such as human milk fortifiers and modular products, nutritional supplements and WIC-eligible nutritionals.

Infant Formula – also defined as a non-exempt formula – a routine formula labeled for use by full term, generally healthy infants or toddlers. Such formulas include milk-based, soy-based, low-lactose, and added rice starch products. Infant formula may be contract or non-contract.

Exempt formula – therapeutic formula intended and labeled for use by individuals with specific medical and/or dietary conditions.

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 digestions via an oral or tube feeding (e.g., Pediasure) and may not be a conventional food, drug, flavoring or enzyme.

**Approval Authority** – designated agency staff who are authorized by criteria outlined in this policy to approved formula, e.g., LVN, RN, LD, RD, Nutritionist and other certifying authorities as specified in Policy CS: 15.0 Certifying Authority. WIC Certification Specialists (WCS) are authorized to approve formula after successful completion of the state WCS formula approval training and with local agency WIC director and preceptor approval. The WCS must be designated “formula certified” to approve selected formulas as designated in the Texas WIC Formulary.

**Health Care Provider (HCP)** – also referred to as “prescriptive authority” – a medical professional who may legally diagnose medical conditions and write prescriptions. In Texas, prescriptive authorities include, but are not limited to, medical doctors (MD), doctors of osteopathy (DO), physician assistant (PA) and nurse practitioners (NP).

**Procedures**

I. **Formula Approval Requirements**
   A. **Prescription**
      1. **Prescription Requirements**-Completed written prescriptions shall include the following information:
         a. Name of participant
         b. Name of formula
         c. Amount needed per day and/or authorized prescribed amount of formula and/or supplemental foods and their amounts (refer to Policy FD: 12.0 for maximum amounts).
         d. Requested length of issuance
         e. Medical diagnosis or reason(s) for which formula or food is prescribed
         f. Contact information for the prescriptive authority
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- g. Signature of the prescriptive authority (signature and/or medical office stamps are acceptable)
- h. Date prescription was written

2. Prescription Documentation - all prescriptions shall be scanned and attached to the MIS.

- a. Acceptable forms - the Texas WIC Medical Request for Formula/Food (F13-06-13153), thereafter referred to as Medical Request Form, and the Texas Medical Request for Medical/Formula/Food are both located at https://dshs.texas.gov/wichd/nut/foods-nut.shtm and are required to provide medical documentation for formula. LA forms are not permitted.
- b. Incomplete prescriptions shall be followed up with a prescription that has the signature/stamp or prescriptive authority. Missing information shall be documented in the “WIC Use Only” section of the Medical Request Form. The original information shall not be altered.
- c. Verbal prescriptions are acceptable.
  - i. Record the information that is received verbally on the Medical Request Form and fax it to the HCP for signature.
  - ii. Staff may accept the verbal RX and issue for the current month.
  - iii. After the signed form is received from the HCP, the formula may continue to be issued for the length of time requested as specified in the Texas WIW Formulary.
  - iv. Scan and attach to the MIS.
- d. Changes, such as a different formula or a new diagnosis, obtained after discussion with the HCP, shall be documented in the “WIC Use Only” section of the Medical Request Form.
e. An existing expired written medical request may be extended for exempt/WIC-nutritionals only by contacting the HCP for verbal approval. This extension may occur once for up to six months if:
   i. the previous medical request is not more 30 days past the expiration date, and
   ii. the diagnosis and formula have not changed, and
   iii. documentation in the “WIC Use Only” section of the Medical Request Form includes:
      a) new length of issuance
      b) name of HCP providing verbal authorization
      c) date of phone conversation
      d) signature of CA
f. Faxed/electronic prescriptions are acceptable.
g. Requests for formula on non-WIC forms
   i. Non-WIC forms shall be official documents from the prescribing entity such as hospital prescriptions, HCP prescription pad, discharge papers. These may be accepted if:
      a) The documents contain all prescription requirements listed in Procedure II.A., and
      b) The participant is an infant less than six months of age and supplemental foods are not an option during issuance time frame and all other needed information is available.
   c) If one of the above documents is presented and it doesn’t not contain the necessary requirements and the HCP cannot be contacted to obtain missing information; the formula may be approved for one month if the document contains at least the following information:
      • date
      • Hospital name or other identifying information
      • Name of formula
• Patient or guardian name.
• Reason for issuance can be clearly inferred (e.g., less than or equal to 37 weeks’ gestation or birth weight less than or equal to 5lbs. 8oz.)

h. Products prescribed for inborn-errors of metabolism (e.g., PKU) require a completed Texas WIC Medical Request for Metabolic Formula/Food (stock no, EF-16-03-13158) from a qualified metabolic Center listed on the back of the metabolic prescription form. If center is not listed, contact the SA. The metabolic form is available at http://dshs.texas.gov/wichd/nut/foods-nut.shtm. For additional information refer to FD: 16.1.

3. Nutrition Assessment
   a. A complete nutrition assessment is required under the following circumstances:
      i. When weight gain or growth need to be monitored
      ii. When staff contact the SA for a formula approval decision, except for metabolic formulas.

   b. The following information shall be included in a nutrition assessment and considered for the formula approval decision:
      i. Anthropometric measurements – weight and length will be entered on the growth chart. Measurements can be obtained by the HCP.
      ii. Enter the date measurements were taken.
         a) measurements obtained from HCP shall not be older than 30 days for infants, children and women.
         b) it is best practice to use measurements that were taken within 7 days for infants.
         c) Current weight and height may be critical to the care of medically fragile infants or children diagnosed as failure-to-thrive.
d) Use professional judgement when deciding to use measurements that are older than 7 days old.

e) Contact the SA if measurements are beyond the 30 day timeframe.

f) If a growth problem is identified during the assessment, the HCP shall be notified (by phone, fax, or letter) if the HCP has not assessed the infant since the formula was last prescribed. A growth problem is defined as weight loss, inadequate or no weight gain, or excessive weight gain.

2. Dietary Intake/dietary history (as needed for approval decision)

3. Formula history

4. Pertinent medical history (as needed for approval decision)

5. Special accommodations for an assessment shall be offered to families with special health care needs (refer to Policy:07.0). If physical presence waiver is in place, use the most recent measurements when available.

6. At a minimum, all non-contract formula approvals shall include a formula history which consists of a review of formulas tried and symptoms experienced.

7. Refer to Texas WIC Formulary [http://dshs.texas.gov/wichd/nut/foods-nut.shtm](http://dshs.texas.gov/wichd/nut/foods-nut.shtm) for the nutrition assessment requirements for each formula.

II. Documentation for formula approval – see Clinic Assessment Manual for more details.

A. The following fields shall be entered in the MIS:

   1. Food package codes
   2. Formula code
   3. Prescription start and expiration date the last day of the month for which the formula is prescribed)
   4. Restricted supplemental foods shall not be issued, if appropriate
B. Participant record will include:
   1. Name of appropriate LA or SA staff approval person
   2. Date the formula was approved or denied
   3. Reason for denial, if applicable
   4. Notification of denial, if applicable Staff shall notify the HCP if the requested formula cannot be issued or is not approved by WIC. This notification may be done by phone, fax or email.
   5. Any additional useful information to support approval or denial of formula.

C. Other formula considerations –
   1. If a participant requests to change from a non-contract formula to a contract formula and the HCP cannot be reached to verify, use the Texas WIC Formula Change Form.
   2. See CAM for instructions for the use of the form and for any other formula considerations

III. WIC staff formula approval authority information

A. Reference materials can be found at http://dshs.texas.gov/wichd/nut/foods-nut.shtm. The following documents shall be referred to when approving formula:
   1. Texas WIC Formulary – includes:
      a. Reason for issuance
      b. Description of product
      c. Maximum length of issuance
      d. Nutrition assessment instructions
   2. Formula Code list – for formula codes and other information regarding packaging and ordering formula

B. Local Agency approvals

   1. Approval authorities shall approve any formula listed in the Texas WIC Formulary (with the exception of formulas requiring SA approval) under the following conditions:
      a. prescription is complete, signed and does require any clarification from the HCP
b. qualifying condition or medical reason is the same as that listed in the Texas WIC Formulary

2. For the Formula Certified (FC) – WCS – may only approve formulas designated as FC-WCS. These are noted in the Texas WIC Formulary and the Nutrition Assessment Guide.

3. If the formula is requested for a reason not found in the Texas WIC Formulary, consult with LA RD or the SA.

4. The LA RD, using professional judgement, may approve these formulas (with the exception of metabolic formulas) for valid medical reasons not listed in the Texas WIC Formulary. Documentation of the reason for approval is required.

5. If information is missing on the Medical Request Form, appropriate LA staff shall contact the HCP to obtain the information.

6. If any other aspect of the request requires discussion with the HCP, refer to the LA nutritionist, RD or the SA for guidance before calling the HCP.

7. WCS may not contact the HCP to discuss or clarify requests unless so directed by a CA.

C. SA approval – for formulas requiring SA approval per the Texas WIC Formulary, contact the SA before contacting the HCP.

1. Formulas that require state agency approval are indicated in the Texas WIC Formulary. These include but are not limited to:
   a. first time metabolic requests
   b. human milk fortifiers
   c. 24 calorie or higher ready to sue formulas for premature infants
   d. modular products

2. The SA shall also be contacted:
   a. when a LA RD is not available
   b. when prescribing formula is:
      i. prescribed for reasons other than those in the Texas WIC Formulary and the LA RD needs assistance and/or,
ii. not listed in the formulary and/or,
iii. not described in any guidelines or memos issued by SA, and/or
iv. for consultation or technical assistance at any time