

Nutrition Services Department of State Health Services

Effective October 1, 2016

Policy No. FD:16.0

Approval of Non-Contract Formulas

Purpose

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

Authority

7 CFR Part 246.10; State Policy

Policy

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

Definitions

Formula(s) – The term “formula(s)” 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 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, or 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

<p style="text-align: center;">Nutrition Services Department of State Health Services</p>

Effective October 1, 2016

Policy No. FD:16.0

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 (e.g., Pediasure); and may not be a conventional food, drug, flavoring, or enzyme.

Non-Contract Infant Formula—Infant formula not covered under the current rebate contract for Texas WIC.

Approval Authority - Designated agency staff who are authorized by criteria outlined in this policy to approve formula; e.g., L.V.N., R.N., L.D., R.D., Nutritionist, and other Certifying Authorities (C.A.) as specified in policy CS: 15.0 *Certifying Authority*. Certified WIC Certification Specialists (WCS's) are authorized to approve formula after successful completion of the state WCS formula approval training and with local agency (LA) WIC director and preceptor approval. The Certified 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 (M.D.), doctors of osteopathy (D.O.), physician assistants (P.A.), and nurse practitioners (N.P.).

Prescription(s) - Medical documentation required to approve formula.

Procedures

- I. Formula approval requirements
 - A. Prescription
 1. Prescription documentation - *The Texas WIC Medical Request for Formula/Food F13-06-13152* (hereafter referred to as Medical Request form), and the *Texas WIC Medical Request for*
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<p style="text-align: center;">Nutrition Services Department of State Health Services</p>

Effective October 1, 2016

Policy No. FD:16.0

Metabolic Formula/Food both located at <http://dshs.texas.gov/wichd/nut/foods-nut.shtm> are required to provide medical documentation for formula. LA developed forms are not permitted.

- a. Incomplete written prescriptions shall be followed up with a phone call to the HCP to obtain any missing information provided the prescription has the signature/ stamp of the prescriptive authority. Missing information shall be documented in the "For WIC use only" section of the Medical Request form. The original prescription information shall not be altered.
- b. Verbal prescriptions are acceptable. Record the information that is received verbally on a Medical Request form and fax it to the HCP for a signature. Staff may accept the verbal RX and issue the requested formula for one month. After the signed form is received back from the HCP, the formula may continue to be issued for the length of time requested as specified in the Texas WIC Formulary. The Medical Request form shall be filed in the participant's chart.
- c. Changes (such as a different formula or a new diagnosis), obtained after discussion with the HCP may be documented in the "for WIC use only" section of the Medical Request form.
- d. Extending an existing written medical request – A recently expired medical request may be extended for exempt formulas/WIC eligible nutritionals only by contacting the HCP for verbal approval. This extension may occur once and for up to 6 months under the following select circumstances:
 - i. The previous medical request is no more than 30 days past the expiration date.

<p style="text-align: center;">Nutrition Services Department of State Health Services</p>

Effective October 1, 2016

Policy No. FD:16.0

- ii. The diagnosis and formula requested have not changed.
 - iii. Documentation in the “for WIC use only” section of the Medical Request form includes:
 - 1) New length of issuance
 - 2) Name of HCP providing verbal authorization
 - 3) Date of phone conversation
 - 4) Signature of CA
 - e. Faxed/electronic prescriptions are acceptable.
 - f. Requests for formula received on non-WIC forms. Non-WIC forms shall be official documents from the prescribing entity such as: hospital prescriptions, HCP prescription pad, discharge papers or summaries. These may be accepted if:
 - i. The documents contain all prescription requirements listed in section IA.2. of this policy or;
 - ii. The participant is an infant less than 6 months of age and supplemental foods are not an option during the issuance time frame and all other needed information is available or;
 - iii. One of the above documents is presented and the HCP cannot be contacted, the formula may be approved for one month if the document contains at least the following information:
 - 1) Date
 - 2) Hospital name or other identifying information
 - 3) Name of formula
 - 4) Patient or guardian name
 - 5) Reason for issuance can be clearly inferred (e.g., ≤37 weeks gestation or birth weight less than or equal to 5lbs. 8oz.)
 - g. If a prescription is received that requires additional information, clarification, discussion, etc. and the HCP
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<p style="text-align: center;">Nutrition Services Department of State Health Services</p>

Effective October 1, 2016

Policy No. FD:16.0

- cannot be reached, call the State Agency (SA) formula pager at (512) 499-6814 if needed, for assistance.
2. Prescription requirements - Completed written prescriptions include the following information:
 - a. Name of participant
 - b. Name of formula
 - c. Amount needed per day and/or;
 - d. Authorized prescribed amount of formula and/or supplemental foods and their amounts (see Policy *FD: 12.0 Food Packages* for maximum amounts)
 - e. Requested length of issuance
 - f. Medical diagnosis or reason(s) for which formula or food is prescribed
 - g. Contact information of the prescriptive authority
 - h. Signature of the prescriptive authority (signature and/or medical office stamps are acceptable)
 - i. Date prescription was written
- B. Nutrition assessment –
1. A complete nutrition assessment is required under the following circumstances:
 - a. When weight gain or growth need to be monitored.
Examples: Neosure or Enfacare for prematurity or low birth weight, and Pediasure or Kid Essentials for failure to thrive, etc.
 - b. When staff contact State Agency (SA) staff for a formula approval decision. This includes State Approval formulas excluding metabolic formulas.
 2. The following information shall be included in a nutrition assessment (when one is completed) and considered for the formula approval decision:
 - a. Anthropometric measurements – weight and length/height shall be plotted on the growth chart. Measurements can be
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<p style="text-align: center;">Nutrition Services Department of State Health Services</p>

Effective October 1, 2016

Policy No. FD:16.0

- obtained from the HCP. Use the date the measurements were taken to plot on the growth chart.
- i. Measurements obtained from the HCP shall not be older than 30 days for infants, children, and women.
 - ii. It is best practice to use measurements that were taken within 7 days for infants.
 - iii. Current weight and height may be critical to the care of medically fragile infants or children diagnosed with failure-to-thrive.
 - iv. Use professional judgment when deciding whether to use measurements provided that are older than 7 days.
 - v. Contact the formula pager at (512) 499-6814 if measurements are beyond the 30 day timeframe.
 - vi. For preterm infants, corrected weight and length for age shall be plotted up until the infant/child is 2 years chronological age.
 - vii. If a growth problem is identified during an assessment, the participant's HCP shall be notified (by phone, fax, or letter) if the HCP has not assessed the participant since the formula was last prescribed. A growth problem is defined as weight loss, inadequate or no weight gain, or excessive weight gain.
- b. Dietary intake/dietary history (as needed for the approval decision)
 - c. Formula history
 - d. Pertinent medical history (as needed for the approval decision)
3. At a minimum, all non-contract formula approval requests shall include a formula history which consists of a review of formulas tried and symptoms experienced.
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<p style="text-align: center;">Nutrition Services Department of State Health Services</p>

Effective October 1, 2016

Policy No. FD:16.0

4. Refer to the *Texas WIC Formulary* for the nutrition assessment requirements for each specific formula.
- C. Length of approval
1. The approval authority shall determine how long a formula shall be issued based on length of time a formula is requested, the participant's health history and nutrition assessment (if completed).
 2. A prescription may be approved for the full length of time requested.
 3. It may also be approved for a shorter length of time than requested. The original prescription is still valid if approved for a shorter length of time.
 4. Prescriptions that cross certification expiration dates may be extended for the remaining length of the request at the time of certification.
Example: Neocate Jr. is approved January 2nd for 6 months. The approval time period is January through June. The certification expires at the end of February. Initial issuance is for 2 months (January – February). Four additional months may be issued after the certification is entered in February. No further formula approval is needed at that time.
 5. Specific details on length of issuance can be found in the *Texas WIC Formulary* located at:
<http://dshs.texas.gov/wichd/nut/foods-nut.shtm>. Additional requirements may apply to specific formulas.
- II. Documentation for formula approval – The *Formula Approval Form* located at: <http://dshs.texas.gov/wichd/nut/foods-nut.shtm> (or locally developed form) may be used for formula approval documentation when indicated.
- A. Texas WIC information network (TWIN) documentation – the following fields shall be entered into TWIN:
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<p style="text-align: center;">Nutrition Services Department of State Health Services</p>

Effective October 1, 2016

Policy No. FD:16.0

1. Food package code
 2. Formula code
 3. Prescription expiration date (the last day of the month for which the formula is approved)
 4. Restricted supplemental foods shall be refused if appropriate
 - B. Participant record documentation
 1. Name of the appropriate LA or SA staff approval person
 2. Date the formula is approved
 3. Reason(s) for denial, if appropriate
 4. Notification of denial, if applicable
 5. Any additional useful information to support approval or denial of formula
 - C. Notifying HCP – Staff shall notify the HCP if the requested formula cannot be issued or is not approved by WIC. This notification may be by phone, fax or email.
 - D. Other formula approval considerations
 1. When an exempt formula/ WIC eligible nutritional has been prescribed for a valid medical condition, do not challenge with or issue a different formula without first obtaining approval from the prescriptive authority.

Example: Neocate DHA/ARA was prescribed for severe multiple allergies including cow and soymilk allergies. Do not issue a protein hydrolysate (e.g., Nutramigen LGG) without HCP approval.
 2. A participant does not need to be challenged on contract formula prior to issuing an exempt formula/WIC-eligible nutritional.

Example: Nutramigen LGG was prescribed for cow milk allergy. A trial of contract soy formula does not need to occur first.
 3. Prematurity classification – If the HCP does not write “prematurity or low birth weight” as the diagnosis for a formula
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Nutrition Services Department of State Health Services

Effective October 1, 2016

Policy No. FD:16.0

typically requested for an infant less than or equal to 37 weeks gestation assume that prematurity is the diagnosis.

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

III. Approval of non-contract infant formula – Refer to the form “*Non-Contract Infant Formula Approval Guidance*” and/or the policy sections A-E below.

- A. New Texas WIC participants born (or initially certified) on or after 10/1/16 will no longer be eligible to receive non-contract infant formulas.
- B. Participants previously prescribed these formulas may continue to be eligible for them if they meet the following criteria:
 1. Date of birth (DOB) (or initially certified) on or prior to 9/30/16.
 2. Previous issuance of a non-contract infant formula from Texas WIC.
 3. Presentation of a completed prescription form with one or more qualifying medical conditions.
- C. After evaluation and approval by appropriate LA or SA staff, the formula may be issued until the prescription expiration date.
- D. Evaluation consists of review of the prescription form and comparison with the latest version of the *Texas WIC Formulary*.
- E. Contract formula retrials are no longer required every 3 months. Instead, a trial of contract formula is required after the end of the prescription expiration date, unless medically contraindicated.

Example: Enfamil AR was issued and approved prior to 10/1/16. A new RX was presented on 10/10/16 for 6 months (no benefits in hand). The retrial is now required in March 2017 prior to the next approval time period which begins in April 2017.

1. If a contract formula has not been tried since the last approval and no medical contraindication was provided, a primary
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<p style="text-align: center;">Nutrition Services Department of State Health Services</p>

Effective October 1, 2016

Policy No. FD:16.0

contract formula or an alternate contract formula (with complete and valid prescription) may be provided.

2. If a contract formula has not been tried since the last approval and the parent or guardian refuses a retrial, contact the HCP for permission for a retrial or a medical contraindication to refuse the retrial.
3. If a participant requests to change from a non-contract infant formula to a contract infant formula and has a current valid prescription for the non-contract infant formula:
 - a. Attempt to verify the change with the HCP that wrote the original prescription. This may be accepted verbally.
 - b. If the HCP cannot be reached, inform the HCP of the formula change via fax. The faxed form used to inform the HCP must include:
 - i. Name of participant and date of birth
 - ii. Clinic name and contact information
 - iii. The names of the current formula and the new formula requested
 - iv. A signed statement from the participant indicating acknowledgement of the requested formula change.
 - c. One final month of the original formula may be provided pending any possible medical objections from the HCP.
 - d. An optional form has been created for this purpose. It is entitled; "Texas WIC Formula Change" form and can be found at: <http://dshs.texas.gov/wichd/nut/foods-nut.shtm>.

IV. 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* – The formulary includes:
 - a. Reasons for issuance
 - b. Description of product
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<p style="text-align: center;">Nutrition Services Department of State Health Services</p>

Effective October 1, 2016

Policy No. FD:16.0

- c. Maximum length of issuance
 - d. Nutrition assessment instructions
 - 2. *Formula Maximum Quantity Table* – For maximum quantities of formula by age and feeding option
 - 3. *Formula Code List* – For formula codes and other information regarding packaging and ordering formula
 - B. LA Approvals
 - 1. Approval authorities shall approve any formula listed in the *Texas WIC Formulary* (with the exceptions listed in Section IV.C.) under the following conditions:
 - a. Prescription is complete, signed and does not require any clarification by the HCP.
 - b. Qualifying condition or medical reason is the same as that listed in the *Texas WIC Formulary*.
 - 2. If the formula is requested for a reason not found in the Texas WIC formulary, consult with a LA RD or SA.
 - 3. The LA RD, using professional judgment, 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.

Example: The following situation would be outside the guidelines for this formula as described in the Texas WIC Formulary - EnfaCare request for a 13 month old child, born at 34 weeks gestation who was 4 lbs. at birth, developmentally delayed and not eating baby food. The LA RD could make a determination and decision without contacting the SA for approval. A brief description of the reason for the decision is to be included in the formula approval documentation.
 - 4. Formulary approval exceptions by LA RD's may not conflict with other policy restrictions.
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<p style="text-align: center;">Nutrition Services Department of State Health Services</p>

Effective October 1, 2016

Policy No. FD:16.0

Example: Similac Sensitive RTU due to intolerance symptoms on powder is in conflict with *FD: 15.0 Issuance of Ready-to-Use Formula*. Such medical exceptions are to be referred to SA formula approval staff.

5. If information is missing on the Medical Request form, appropriate LA staff shall contact the HCP to obtain the information.
 6. If the missing information is limited to length of issuance, date, or signature, any staff member may call the HCP or fax back the request to be signed.
 7. If any other aspect of the request requires discussion with the HCP, refer to the LA nutritionist, RD or SA for guidance before calling the HCP.
 8. 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 office approval are indicated in the *Texas WIC Formulary*. These include but are not limited to:
 - a. First time metabolic requests
 - b. Human milk fortifiers (HMF)
 - c. 24 calorie or higher ready-to-use (RTU) formulas for premature infants
 - d. Modular products
 2. The SA shall also be contacted:
 - a. When a LA RD is not available
 - b. When prescribed formula is:
 - i. prescribed for reasons other than those listed in the *Texas WIC Formulary* and the LA RD needs assistance;
 - ii. not listed in the *Texas WIC Formulary* and/or;
 - iii. not described in any guidelines or memos issued by the SA;
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Nutrition Services
Department of State Health Services

Effective October 1, 2016

Policy No. FD:16.0

c. For consultation or technical assistance any time.