

<p style="text-align: center;"><b>Texas WIC</b> <b>Health and Human Services Commission</b></p>
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Effective May 1, 2023

Policy No. FD:16.0

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## **Approval of Non-Contract Formula**

### **Purpose**

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

### **Authority**

7 CFR 246.10

### **Policy**

Authorized local and state agency (SA) staff may approve the issuance of therapeutic formulas to women, infants, or children for valid medical conditions with a Medical Request from a health care professional (HCP).

Local agency (LA) Certifying Authorities (CAs) are authorized to approve therapeutic formula(s) when the qualifying condition criteria in the Texas WIC Formulary are met.

LA Registered Dietitians (RD) are authorized to make approval decisions based on their professional judgement when qualifying conditions are not consistent with Texas WIC Formulary criteria.

Formula Certified WIC Certification Specialists (FC-WCS) are authorized to approve formulas that are labeled as FC-WCS and meet qualifying condition criteria in the Texas WIC Formulary. FC-WCS are not authorized to contact HCP regarding clarification of qualifying conditions, supplemental foods, or clarifying formula quantities unless directed by a CA.

SA approval is required for: metabolic formulas, human milk fortifiers, 24 calorie or higher ready-to-use (RTU) formulas, modular products and any other product designated for SA approval in the Texas WIC Formulary. SA

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formula approval team is available to make approval decisions when the LA RD is unavailable and/or requests assistance.

Multiple formulas may be approved for one participant based on need if the total allotment of all formulas does not exceed maximum monthly allowance (MMA).

## **Definitions**

Formula – the term “formula” used throughout this policy refers to all types of formula. These include:

- 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.
- Metabolic Formula - Products prescribed for inborn errors of metabolism.
- Therapeutic formula – Formerly defined as “exempt formula”- formula intended and labeled for use by individuals with specific medical and/or dietary conditions, also referred to as exempt formula in federal regulations.
- 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.

Health Care Professional (HCP) – for the purposes of this policy, a health care professional who is authorized to write medical prescriptions in the State of Texas. This includes medical doctors (M.D.), doctors of osteopathy (D.O.), physician assistants (P.A.), and nurse practitioners (N.P.).

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Maximum Monthly Allowance (MMA) – the federal maximum quantity of formula available to a participant monthly, based on age and assigned food package.

Qualified Genetic Centers – A list of recognized medical centers staffed by genetic specialists who can diagnose and treat inborn errors of metabolism and metabolic dietitians trained to counsel and treat patients with appropriate metabolic diets, including metabolic formula. The list is maintained by the Texas Department of State Health Services. [Genetic Provider list](#)

## Procedures

- I. Review and evaluate prescription (RX) information
  - A. Medical requests must contain the following information which is included in the Texas Medical Request for Therapeutic Formulas form (available [here](#)):
    1. Name of WIC participant needing the formula.
    2. Name of formula and form, if applicable.
    3. Amount of formula needed per day and authorized supplemental foods and their prescribed amounts.
      - a. If no specific amount is indicated, the maximum amount allowed may be issued.
      - b. For infants that are also receiving breastmilk, follow guidance in FD:10.0 to determine appropriate food package. Consult with the HCP if needed.
    4. Requested length of issuance.
      - a. If section is left blank, contact the HCP.
      - b. If the HCP cannot be reached by phone or fax, issue one month.
    5. Qualifying condition and/or reason(s) formula or food is prescribed.
      - a. Staff may approve premature transitional formulas without documented qualifying condition for infants who were born prematurely or low birth weight.
      - b. If HCP only includes International Classification of Disease (ICD) code(s), call to clarify qualifying condition.

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6. Signature and credentials of prescribing HCP. May accept electronic or stamped signature.
  7. Date WIC medical request form was written.
    - a. If no date is indicated, but date is listed for anthropometrics, issue based on date of measurements.
    - b. If no date is indicated on signature or anthropometrics and the prescriptive authority cannot be reached, issue for one month.
  8. Contact information for the medical office. May accept medical office stamp.
- B. Acceptable forms of medical documentation for formula requests
1. [Texas Medical Request for Therapeutic Formulas form](#) - Staff may accept all current or previous versions of the Texas WIC medical request form. LA forms are not permitted.
  2. Non-WIC forms may be accepted if:
    - a. Document(s) contain all prescription requirements listed above in Section I. a.
    - b. Participant is less than six months old and supplemental foods are not an option during the issuance time frame.
    - c. Discharge papers/hospital documents may be approved for one month if the following information is included:
      - i. Date
      - ii. Hospital name or identifying information
      - iii. Formula name and form, if applicable
      - iv. Patient name
      - v. Reason for issuance is listed or can be inferred (e.g., prematurity or low birth weight)
  3. Verbal requests for a new formula
    - a. Obtain required prescription information verbally from the HCP or medical support staff consulting with the HCP.
    - b. Document the date and name of prescribing HCP.
    - c. Verbal requests may only be issued for one month.
      - i. If verbal authorization is used prior to the 15th of the month, approve only for the current month.
      - ii. If verbal authorization is obtained on or after the 15th, approve through the end of the following month.

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- d. Attempt to obtain written request within two weeks.
  - 4. Requests with missing or unclear information:
    - a. Contact the HCP and obtain verbal instructions or clarification for any missing or unclear information.
      - i. A nurse or medical assistant may verbally relay information missing from Medical Request that has been signed by a prescribing HCP.
    - b. Document information provided by the HCP in the management information system (MIS) in the Notes section of General tab of the Medical Prescription Page.
- II. Collect Nutrition Assessment information
- A. Consult the Texas WIC Formulary, [available here](#), for the following assessment requirements:
- 1. Formula history
    - a. Complete a formula history for all formula requests excluding formulas for inborn errors of metabolism.
      - i. Infants – List all formulas given, symptoms experienced, and approximate length of time offered. If infant is receiving breastmilk, document information on feeding frequency and/or amount provided.
      - ii. Children – List any formulas given after 12 months of age, symptoms experienced, and length of time offered.
  - 2. Complete assessment
    - a. For formula requests related to conditions that affect growth, as specified in the Texas WIC Formulary, assess the following:
      - i. Diet history – list all food and drinks, including breastmilk and infant formula, consumed in a typical 24-hour period.
      - ii. Relevant medical history
      - iii. Most recent anthropometrics available
        - a) Plot on appropriate growth chart using date of measurements. Ensure appropriate gestational age is input in the MIS.
        - b) Measurements should be within last 14 days for infants and 30 days for women and children.

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1. If measurements are unavailable for infant or child within required timeframe, LA RD or SA may assess for exceptions.
2. Measurements from HCP are acceptable, either verbally from HCP staff or in writing. Document in MIS if measurements are obtained from HCP.
- b. If a growth problem is identified at WIC, refer to the HCP and follow LA High-Risk Referral policy per CS:33.0.
- c. Request for high calorie concentration
  - i. Confirm parent/guardian has received and understands mixing instructions.
  - ii. Contact HCP or SA formula team for assistance, as needed.
- d. When a prescription is approved for a shorter time period than originally requested by the HCP, staff should re-assess and document relevant nutrition information at subsequent approvals.

### III. Document in MIS

- A. Document all relevant assessment information in the Notes section on the General tab of the Medical Prescription page in the MIS.
  1. LAs may determine a different location for storing documentation but must maintain consistency across the LA. LAs must provide their staff with written instructions for alternative documentation locations.
  2. Document alternative location in the Notes section of the Medical Prescription Page.
- B. Upload the WIC medical request form no later than close of business on the day of the creation of the medical request.

### IV. Make an Approval Decision

- A. Consult the Texas WIC Formulary to determine if formula request can be approved.
- B. Determine the length of approval. Prescription expiration dates will always end on the last day of a calendar month. Use the following guidelines to determine how long a prescription is valid.

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1. For initial prescriptions:
  - a. If written in the month before it is presented to WIC, begin length of issuance count with the current month.
  - b. If written in first 10 days of the current month and presented to WIC within the first 10 days of the month, begin length of issuance count with the current month.
  - c. If written any day of the current month and presented to WIC on or after the 11<sup>th</sup> of the month, begin length of issuance count with the following month. Include issuance of the formula for any remaining days in the current month.
2. For repeat prescriptions (renewals):
  - a. If previous approval does not include the current calendar month, follow the same guidance as with initial prescriptions.
  - b. If previous approval includes the current calendar month and the prescription was written within the previous 30 calendar days, begin length of issuance count with the following month.
3. For prescriptions written more than 30 days prior, calculate length of issuance as though the prescription was presented to WIC on the day it was originally signed by the HCP.
4. Formulas can be approved for less than the length of issuance requested for follow-up and/or reassessment at CA or SA discretion.
- C. Before denying a formula request, ensure you have gathered all information.
  1. FC-WCS should defer final denial decision to the CA.
  2. CAs should consult with local or state RD prior to denying formula based on qualifying condition.
  3. Contact the HCP for additional information or to discuss alternative options if appropriate.
  4. Notify HCP of denial and reason for denial by phone or fax.
  5. Document reason for denial and method of HCP notification in Notes section in General tab of the Medical Prescription page in the participant's record.
- V. Approve or Send for Approval in MIS.
  - A. For formulas that can be approved by the LA:

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1. Choose "Request for Approval" for formulas that will be locally approved and follow any LA protocol.
  2. Choose "Request for State Approval" if needed (i.e. local RD is unavailable or seeking further guidance).
  - B. For formulas that can only be approved by the SA:
    1. Before submitting formula request to the SA:
      - a. Ensure Medical Request form is uploaded.
      - b. Document and plot anthropometrics, when required.
      - c. Include all relevant assessment notes and staff contact information (direct phone or email) in the Notes section on the General tab of Medical Prescription page.
    2. Select "Request for Approval." Only one option will be available in the MIS when formula requires SA approval.
    3. If SA staff does not respond within 15-20 minutes, email the State Formula Team: [FormulaTeam@hhs.texas.gov](mailto:FormulaTeam@hhs.texas.gov)
- VI. Extending an expired WIC medical request form
- A. CAs may contact the HCP's office for verbal authorization from the HCP or medical support staff consulting with HCP to extend an expired medical request form once, for up to six months, when the following conditions exist:
    1. Previous medical request form is not more than 30 days past the expiration date.
    2. Qualifying diagnosis and requested formula have not changed.
  - B. Document the extension by creating a new medical request in the MIS. Include:
    1. Updated length of issuance
    2. HCP name providing verbal authorization
    3. Location of original Rx (or upload a copy to the new request)
    4. Note explaining this is an extension
  - C. Use professional judgment for re-assessment of nutrition information and anthropometrics when approving extensions for more than one month.



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- VII. Changing from therapeutic formula to contract formula by parent/caregiver choice – If a parent/caregiver requests a change to a contract formula during the valid period of the WIC medical request form:
- A. Contact the HCP to confirm the change. Document the name of the HCP or medical support staff and any guidance provided in the Notes section of the participant’s page.
  - B. If unable to reach the HCP by phone, contact SA for guidance.
- VIII. Metabolic formula requests for inborn errors of metabolism
- A. Require a completed [Texas WIC Medical Request for Metabolic Formula/Food](#) (stock no. EF-16-03-13158) or the equivalent information from a genetic/metabolic specialist at a qualified genetic center.
    - 1. Number of cans and/or containers needed monthly or mixing instructions must be provided by the genetic/metabolic specialist.
    - 2. Old version of the Texas WIC Medical Request for Metabolic Formula/Food form may be accepted if all information is included.
    - 3. If Metabolic Formula request is presented on standard Texas WIC Medical Request Form:
      - a. Confirm the request was written by a genetic/metabolic specialist. Contact the specialist for any missing information and document in the Notes section of the General Tab of the Medical Prescription page.
  - B. All metabolic formula requests must be approved by SA.
  - C. Requests for metabolic formulas do not require nutrition assessment.
- IX. Approving Non-Contract Formula Requests during disasters
- A. Follow guidance outlined in current SA Disaster Plan and any relevant memos related to the specific disaster.
  - B. For questions or concerns, contact the State Formula Team: [formula.team@hhs.texas.gov](mailto:formula.team@hhs.texas.gov)