

Subject: Therapeutic Formula and WIC-Eligible Nutritionals**Item: Provision of Therapeutic Formula and WIC-Eligible Nutritionals**

PURPOSE:

Provides information on therapeutic formula and WIC-eligible nutritionals.

POLICY:

WIC staff must issue therapeutic formulas and/or WIC-eligible nutritionals only when access to these products from another healthcare plan or program is not available and a documented medical condition exists. Local agency (LA) staff must obtain medical documentation provided by a health care provider with prescriptive authority prior to issuing:

1. Therapeutic formula, WIC-eligible nutritionals, or any WIC food in addition to therapeutic formula to a participant who has a qualifying medical condition; and
2. The increased formula food package when WIC infant food is contraindicated beyond six months of age.

This will help ensure that participants receive adequate medical documentation and oversight from their healthcare provider when therapeutic formula, WIC-eligible nutritionals, or WIC supplemental food are prescribed.

PROCEDURE(S):

- I. Requesting and Processing Medical Documentation
 - A. Issuance of any therapeutic formula or WIC-eligible nutritionals to WIC participants requires medical documentation every three months. For well-documented, chronic medical conditions, such as severe allergies, medical documentation can be required every six months.
 - B. With a therapeutic formula or WIC-eligible nutritionals prescription the LA must obtain a consent form from the participant prior to contacting the provider.
 - C. Medical documentation must include the following:
 1. WIC Pediatric Referral Form (CDPH 247A) containing:
 - a. Participant's name.
 - b. Date of prescription (Rx).
 - c. Qualifying medical diagnosis/condition(s) for issuance of the WIC-eligible formula or WIC-eligible nutritionals.
 - d. Name of the formula or WIC-eligible nutritionals for the stated medical condition.

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- e. Amount needed per day.
- f. Length of issuance.
- g. WIC-authorized supplemental food restrictions if applicable.
- h. Signature (or signature stamp) and contact information of the health care provider who wrote the Rx.

If medical documentation information is missing, LA staff may obtain information by telephone only when absolutely necessary and on an individual participant basis. The LA must obtain written confirmation of the medical documentation within two weeks of the call and document the information obtained in WIC management information system (WIC MIS) "Family Comments".

- D. Prior to issuing therapeutic formula or WIC-eligible nutritionals, the WIC registered dietitian (RD) or degreed nutritionist (DN) must ensure that a WIC qualifying medical condition is documented by the medical provider and the prescribed formula or WIC-eligible nutritionals requested are consistent with the manufacturer's recommended usage. The RD/DN must contact the health care provider if they determine that the prescribed formula or WIC-eligible nutritionals does not match the diagnosis or they need additional information regarding the qualifying condition.
- E. The LA must not issue a different formula, WIC-eligible nutritionals, or WIC supplemental food without prior approval from the health care provider who prescribed the formula or WIC-eligible nutritionals.
- F. If the prescribed formula or WIC-eligible nutritionals can be printed on a Food Instrument (FI), the LA must print the FIs for the participant and document in WIC MIS whether follow up needs to be made with Medi-Cal or if they have been denied. The LA staff must fax all Medi-Cal denials, the *WIC Pediatric Referral Form* (CDPH 247A) and a participant consent form to CDPH WIC. The participant consent form allows LA and CDPH/WIC staff to share participant information with Medi-Cal, healthcare provider(s) and pharmacy.
- G. If the prescribed formula or WIC-eligible nutritionals cannot be printed on an FI, the LA must fax a copy of the *WIC Pediatric Referral Form* (CDPH 247A), the Medi-Cal denial, and the participant consent form to the CDPH/WIC to request the authorized formula or WIC-eligible nutritionals. The LA shipping address must be included on the fax coversheet. An approval or denial from the CDPH/WIC will be faxed to the LA within three to five business days unless follow-up is needed.

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H. The LA must maintain a file of all medical documentation in a place readily accessible for program evaluation and audit purposes. This file must be separate from the daily files and include:

1. The complete prescription or *WIC Pediatric Referral Form* (CDPH 247A).
2. All faxes sent and received.
3. Denial letters from other medical payers (see WPPM Policy 390-20 for provision of formula by health plans and other programs).
4. Signed consent form.

II. Medical Supervision Requirements

Due to the nature of the medical conditions, close medical supervision is essential for dietary management of participants receiving the food packages with therapeutic formula or WIC-eligible nutritionals.

- A. The participant's health care provider is responsible for medical oversight and instruction.
- B. Qualified LA staff is responsible for ensuring that appropriate WIC nutrition services are provided to participants.

III. Individual Nutrition Tailoring

The LA must issue less than the maximum monthly allowances for prescribed formula, WIC-eligible nutritionals, or WIC supplemental food when:

- A. Medically or nutritionally warranted, i.e., elimination of a food due to a food allergy.
- B. A participant refuses or cannot use the maximum monthly allowances.
- C. Another payer contributes formula or WIC-eligible nutritionals.

The LA must document in WIC MIS "Family Comments" when the maximum monthly allowances are not issued.

See WPPM 320-40 for more information on food package tailoring.

AUTHORITY:

[7 CFR §246.10\(b\)\(2\)\(ii\)](#)

[7 CFR §246.10\(d\)\(ii\) through \(vi\)](#)

21 CFR §107.3

22 CCR §51313.3(e)(2)

Section 412(h) of the Federal Food, Drug and Cosmetic Act 21U.S.C. 350a(h)

FOOD DELIVERY SYSTEM

WPPM #390-10

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Section 412 of the Federal Food, Drug Act (21 U.S.C. 350a)

RESOURCE:

[Therapeutic Formula Training Part 1 \(PPT\)](#)

[Therapeutic Formula Training Part 1 Q and A \(PDF\)](#)

[California Children's Services](#)

[Regional Center](#)

[Child Health and Disability Prevention \(CHDP\)](#)

CROSS REFERENCE:

WPPM 120-10 Access to and Security of Confidential Information

WPPM 320-40 Food Package Tailoring

WPPM 390-20 Coordinating with Healthcare