II. Nutrition Services – Special Formulas and WIC-Eligible Nutritionals for Specialized Medical Needs

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<th>Approved by:</th>
<th>Review by Legal Counsel:</th>
<th>Effective Date: 01/01/2016</th>
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<tr>
<td>LaQuandra S. Nesbitt MD, MPH; Agency Director</td>
<td>Phillip Husband, Esq.; General Counsel</td>
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**I. Authority**

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<th>USDA</th>
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**II. Reason for the Policy**

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<th>Reason</th>
<th>FED § 246.10 Supplemental foods</th>
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**III. Applicability**

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<th>Applicability</th>
<th>CPAs working within DC WIC Local Agencies</th>
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**IV. Policy Statement**

1. **Required Documentation for Prescription**

Authorization is required before issuing checks for any formula other than the rebate (standard) WIC formulas for healthy infants (iron fortified Similac Advance OptiGRO and Similac Soy Isomil). In addition to special formula / WIC-eligible nutritionals, participants will receive a complete food package appropriate for status. When participants have a documented medical condition requiring special formula/medical food, authorization is also required for issuing the supplemental foods.

The qualifying conditions include but are not limited to premature birth, low birth weight, failure to thrive, inborn errors of metabolism and metabolic disorders, gastrointestinal disorders, malabsorption syndromes, immune system disorders, severe food allergies that require an elemental formula, life threatening disorders, diseases and medical conditions that impair ingestion, digestion, absorption or the utilization of nutrients that could adversely affect the participant’s nutrition status.

Formula or medical foods may not be issued solely for:

- (a) Infants whose only condition is:
  - A diagnosed formula intolerance or food allergy to lactose, sucrose, milk protein or soy protein that does not require the use of an exempt infant formula; or
  - A non-specific formula or food intolerance

- (b) Women and children who have a food intolerance to lactose or milk protein that can be successfully managed with the use of one of the other WIC food packages

- (c) Any participant solely for the purpose of enhancing nutrient intake or managing body weight without a qualifying condition
Requiring the health care provider to designate the amount of WIC formula and the WIC supplemental foods allowed in the participant’s diet will help the CPA design nutrition education and a food package prescription that is appropriate to the participant’s medical needs.

Local Agency staff must obtain either a written prescription (a completed ‘DC WIC Prescription and Referral Form’) from a health care professional licensed in the District of Columbia to write medical prescriptions or a documented telephone authorization for that special formula/supplemental food. For telephone authorization, a written medical prescription should be filed in the client’s chart within 30 days. The prescription or telephone authorization must include:

- Date
- Date of birth
- Participant’s name
- Parent or guardian’s name
- Name and form (concentrate, powder, ready-to-use) of special formula or medical food
- Medical diagnosis requiring use of special formula
- Anticipated duration of prescription (not to exceed 6 months)
- Quantity of formula prescribed per day and special feeding instructions including mixing instructions
- Previously tried formulas with start date, end date and results of trial
- Note if medical contraindication to try other formula(s) than the one prescribed
- Physician/provider printed name, address, phone number
- Indicate any foods that WIC should not give this client
- Signature (Requires MD, DO, PA, CNP, CNM signature)

Participants with complete written medical prescriptions may receive bi-monthly (high-risk) check issuance until the prescription end date. When a participant has an incomplete written medical prescription, the CPA may obtain the missing information via telephone. The telephone contact must be documented in the participant’s file. The participant may receive one set of checks and the written medical prescription must be obtained within 30 days.

It is within the scope of practice of a CPA to review breastfeeding goals, formulas (i.e. appropriate for age and medical needs), feeding regimens, and formula recipes. Indications for the use of all formulas are available in Appendix 2.016A – Special Formulas and WIC-Eligible Nutritional by Type of Formula/Medical Food. Supporting documentation and literature are available at the WIC State Agency.

For cases where a prescriptive authority has prescribed a formula or feeding plan that based upon the clinical judgment of the CPA is not appropriate or indicated, the CPA should contact the prescribing authority. The CPA will be prepared to discuss
why the formula is not appropriate or indicated, including documentation of feeding and growth history, and offer acceptable alternatives available on the WIC approved formula list. Any and all interactions with physicians should be documented and placed in the participant’s file.

2. Special Formulas for Infants and WIC-Eligible Nutritionals for Women & Children with Special Dietary Needs

Available DC WIC special formulas/eligible nutritionals are listed in Appendix 2.016B – DC WIC Special Formulas/Eligible Nutritionals Alphabetical Listing. For indications of using a specific formula, refer to Appendix 2.016A – Special Infant Formula/WIC-Eligible Nutritionals by Type of Formula/Medical Food.

3. Supplemental Foods for Women, Infants and Children with Special Dietary Needs

In addition to special medical formula/food, participants with qualifying medical conditions receive full food prescriptions according to the status, age and/or breastfeeding amount. When a participant has a qualifying condition which requires the use of special formula/medical food, the prescriptive authority must also approve the issuance of the supplemental foods. Refer to Appendix 2.016D – Food Packages for Participants with Qualifying Medical Conditions for details on the food packages. See Policy and Procedure 2.012 – Prescribing DC CARES Food Packages for further information on issuing food packages.

V. Definitions & Acronyms

Acronym:
Competent Professional Authority (CPA)

Definitions:
- ‘Premature Infant’ – born at 37 or less weeks gestation
- ‘Low Birth Weight Infant’ - birth weight < 2.5 kg (5.5 pounds)
- ‘Very Low Birth Weight Infant’ - birth weight < 1500 grams (3.125 pounds)

VI. Procedures

Refer to Appendices for information on prescribing specialized formulas and supplemental foods to women, infants and children with qualifying medical diagnosis.

1. Requirement for Documentation

Hospital discharge papers can be used in lieu of a prescription or a completed DC WIC Prescription and Referral Form (Appendix 2.016C) for up to two (2) months of checks when the required information is included within the discharge papers. Follow up is required for issuance beyond two months and a written prescription or the completed referral form must then be included in the participant’s WIC chart. When a participant’s food prescription is changed to a special
formula/medical food, the medical condition must be documented in the participant’s electronic folder in the TGIF note. This is necessary since DC CARES does not currently allow an update of nutrition risk factors outside of a certification. Additionally, since the participant becomes high-risk due to the medical condition, an alert must be placed on the electronic file to indicate the participant is high-risk.

2. Issuance of Infant Formula

a. Prescription for special formula/medical foods and supplemental foods not available in DC CARES

If a prescription completed by a prescriptive authority for a therapeutic formula is received that is not on the list of available Special Formulas/Medical Foods, contact the physician/provider and fax him/her the summary sheet of DC WIC Special Infant Formula/Medical Foods List and discuss appropriate formula substitutions (refer to Appendix 2.016A – DC WIC Special Infant Formula/Medical Foods by Type). Contact the State Agency in cases where no resolution of the problem can be reached.

b. Recommended maximum issuance duration of special formula / supplemental foods

The recommended maximum duration of a prescription for special formula for infants is three (3) months. The maximum duration of a prescription for children and women with special dietary needs shall be six (6) months. The CPA may allow a physician to exceed the maximum issuance duration, but must document justification in the TGIF note of the participant’s DC CARES file. Maximum issuance duration of formula should be monitored during subsequent clinic visits. Refer to Appendix 2.012B – Food Prescription for Infants in regard to documenting the prescribed duration of a special infant formula in DC CARES.

c. Additional amount of infant formula

Infants 6 months of age or greater whose medical condition prevents them from consuming complementary infant foods (cereal, fruit and vegetables, and meat) may receive exempt infant formula or WIC-eligible nutritionals at the same maximum monthly allowance as infants ages 4 - 5 months of the same feeding option. The provision of exempt infant formula or WIC-eligible nutritionals for these infants is in lieu of provision of complementary infant foods.

d. Guidance on prescribing special formula for Premature, Low Birth Weight and Very Low Birth Weight Infants
A Premature Transition (Discharge) Formula such as Similac NeoSure (22 cal/fl oz) or Enfamil NeuroPro (22 cal/fl oz) may be issued when a doctor identifies the participant as premature, low birth weight, or very low birth weight. The medical provider’s prescription needs to be presented by the authorized representative when requesting a special formula. The prescription must document the medical reason, quantity and duration for the prescribed formula. This information must be kept in the participant’s chart.

Approved medical reasons are: preterm or premature infant, infant with low birth weight or very low birth weight, and/or there is a need for higher levels of specific nutrients for continued growth.

There are no circumstances where Enfamil Premature, Similac Special Care Advance, or Human Milk Fortifier will be provided, even with a physician’s prescription. Infants who are stable for discharge from the hospital should be able to thrive on a Premature Transition (Discharge) formula or a standard infant formula (i.e. Similac Advance OptiGRO). Infants requiring additional calories may do so with a concentrated Premature Transition formula or standard infant formula. These formulas may also be added to breastmilk to concentrate calories. Soy based infant formula is not appropriate for use in preterm infants.

e. Procedure for issuance of Similac Sensitive for Spit-Up

Local Agency staff is required to maintain detailed documentation of the medical condition and progress of the infant. This documentation will include a prescription with all required information and TGIF notes as appropriate.

Similac Sensitive for Spit-Up will only be approved for use in infants with diagnosed Gastro Esophageal Reflux Disease (GERD) and Failure to Thrive (FTT). These infants may also be using co-therapies that address poor growth, positioning, encouraging smaller frequent feeds and/or medications (Zantac, Protonix). This formula shall not be prescribed for thriving infants with GERD and is not recommended for use in pre-term infants. All requests for Similac Sensitive for Spit-Up must be referred to the CPA for intervention.

- CPAs will verify all documentation
- CPAs will counsel caregivers about the appropriate use of this special formula
- Similac Sensitive for Spit-Up will be approved in two month increments only, until it is no longer medically necessary

f. Procedure for issuance of Similac Total Comfort and Similac Sensitive for Fussiness and Gas
Similac Total Comfort and Similac Sensitive for Fussiness and Gas will only be approved with cow’s milk/soy protein intolerance and gastrointestinal distress which may be due to lactose sensitivity. A prescription with a medical diagnosis of “gassy” or “fussy” will not be accepted for these formulas. All requests for Similac Total Comfort and Similac Sensitive for Fussiness and Gas must be referred to the CPA for intervention.

- CPAs will verify all documentation
- CPAs will counsel caregivers about the appropriate use of these special formulas

g. Procedure for issuance of Nutramigen, Alimentum, Pregestimil

Nutramigen, Alimentum and Pregestimil will only be approved for infants with milk and/or soy protein intolerance/allergy, the prevention of food allergy in high risk infants, and/or gastrointestinal impairments including, but not limited to, malabsorption. These formulas will be approved for use for infants who experience documented FTT with a milk or soy based formula but show improvement with an Extensively Hydrolyzed Protein based formula. Infants should have failed a trial of milk and soy based formula prior to the issuance of these formulas unless directed by a physician. Premature infants who fail a trial of milk based formula do not need to trial soy based formula prior to the issuance of these formulas. Alimentum or Pregestimil is recommended for infants with fat malabsorption or steatorrhea. When Nutramigen and Pregestimil are used, the total calcium content of the diet should be assessed. Nutramigen with Enflora LGG contains probiotics, which are not appropriate for immune-compromised infants. A participant may only receive Nutramigen with Enflora LGG when it is specifically documented in the medical prescription.

h. Procedure for issuance of Neocate, Elecare

Neocate and Elecare will only be approved for infants with multiple food protein intolerance/allergy with severe atopic reactions, transition from TPN, severe GERD and/or other severe gastrointestinal impairments. Neocate and Elecare are nutritionally complete elemental formulas specifically indicated for infants and children who need an amino acid-based medical food or who cannot tolerate intact or hydrolyzed protein. Nutramigen, Alimentum or Pregestimil should have been trialed prior to issuing Neocate or Elecare unless directed by a physician.

i. Procedure for issuance of Similac Soy Isomil for Infants and Toddlers
Although Similac Soy Isomil is indicated for infants 9-12 months and children 12 – 24 months, it is not generally necessary for infants. Similac Soy Isomil contains the same caloric concentration of infant formula (20 cal/oz), but has different nutrient levels. If the child requires an increased calorie concentration, Bright Beginnings Nutritional Pediatric Drink Soy (30 cal/oz) should be used. For children who require soy beverage without increased calories, soy milk should be issued. Medical documentation required.

j. Procedure for issuance of pediatric formula

Pediasure, Peptamen Junior or other 30 cal/fl ounce pediatric formulas may be issued to infants who are unable to tolerate an adequate volume of an infant formula by mouth to meet their caloric needs for growth and development. This may include infants who are significantly fluid restricted or have very high caloric needs. Pediatric formulas will not be issued due to refusal to take infant formula alone. Justification for any formula outside of manufacturer’s recommended age range for formula requires approval from a member of the WIC State Agency nutrition team. Use shall be determined and documented in the TGIF note.

k. Vegan diets and religious reasons for special infant formula/medical food issuance

When the request for a special formula is based on religious eating patterns, medical documentation by a prescriptive authority is required to ensure the prescriptive authority is aware of the special formula usage. This is also required when substituting soy milk or tofu for milk in a child’s diet for religious reasons or a vegan diet. Requiring medical documentation for soy-based beverage for children ensures that a child’s health care provider is aware that the child may be at nutritional risk when milk is replaced by other foods.

l. Procedure for issuance of Prebiotics and Probiotics

When formulas exist both with and without Prebiotics or Probiotics, the medical prescriptions should state whether prebiotics or probiotics are desired. Any prescription discrepancies require follow-up by CPA.

- **Prebiotics** added to infant formulas may increase the amount of good bacteria in the digestive tract, however more studies are needed to demonstrate this and other clinical benefits

- **Probiotics** have been associated with enhanced immunity and assist in supporting healthy gut barrier and balanced immune functions. Probiotics are not appropriate for immunocompromised infants
m. Procedure for issuance of Ready to Use (RTU) Formulas

WIC State agencies must offer formulas/nutritionals in concentrated, liquid, or powder physical forms.

RTU formula may be authorized under certain conditions determined and documented by the CPA in the TGIF note such as:

1. Unsanitary or restricted water supply (i.e. lead contamination of public water supply system)
2. The inability of a caretaker to correctly prepare concentrated or powdered formula
3. The WIC-eligible formula is only available in RTU

For participants with qualifying conditions which require the use of special formula/medical foods, there are two additional circumstances authorized for issuing RTU formula:

- If an RTU formula better accommodates the participant’s condition
- If it improves the participant’s compliance in consuming the prescribed WIC formula.

3. Issuance of 2nd Tier Special Formula/Nutritionals and Issuance of Special Formula/Nutritionals Outside the Manufacturer’s Recommended Age Range

In addition to the special infant formulas listed above, the WIC program provides other metabolic formulas on a case by case basis. Requests for these 2nd tier products need to be made by contacting the WIC State Agency at (202) 442-9397. Approval is given by a member of the WIC State Agency nutrition team.

Justification for any formula outside of the manufacturer’s recommended age range requires approval from a member of the DC WIC State Agency nutrition team.

4. Issuance of supplemental foods to participants with qualifying conditions

Participants with qualifying medical conditions that require the use of a special formula/medical food must also have documented approval for issuing the food package appropriate for the participant. Documentation may be provided on the DC WIC Medical Documentation & Referral Form for Women, Infants and Children or on a medical prescription form. When using this form, the prescriptive authority needs to document supplemental foods that should not be given to the participant.

Whole Milk for Women and Children over 2 Years
Women and children over 2 years old with medical conditions requiring the use of a special formula/medical food may receive whole milk or reduced fat (2%) milk under certain conditions, including but not limited to, underweight and maternal weight loss during pregnancy when documented by a prescriptive authority.

**Fat-Reduced Milks for Children 12 Months to <24 Months**
Children one year of age (12 months to <24 months) may receive fat-reduced milks (2%, 1% or fat free) for whom overweight or obesity is a concern. The CPA may determine the need for fat-reduced milks for young children under Food Package IV based on an individual assessment and consultation with the child’s healthcare provider if necessary. Due to the medically fragile qualifying conditions of children 12 months to 2 years of age, medical documentation for issuance of WIC-eligible formula and foods, including fat-reduced milks, is required under Food Package III.

**Infant Cereal for Children**
Women and children with a qualifying condition that requires the use of a special formula/medical food may receive 32 ounces of infant cereal as a substitute for breakfast cereal with medical documentation.

**Infant Fruit and Vegetables for Women and Children**
Women and children with a qualifying condition that requires the use of a special formula/medical food may receive commercial jarred infant fruit and vegetables in lieu of the cash-value check (CVC). Children may receive 128 ounces of jarred infant fruit and vegetables and women may receive 160 ounces of jarred infant fruits and vegetables. Some participants may prefer to purchase fruits and vegetables via the CVC and process/puree these themselves. This is encouraged for those who would benefit from this method of modifying the consistency and texture of foods to improve nutritional intake.

**Soy Milk and/or Tofu for Children:**
For conditions such as milk allergy, severe lactose intolerance, as well as for vegan diets and religious reasons, children may receive soy milk and/or tofu as a substitute for milk. The CPA may determine the need soy milk and/or tofu as substitutes for milk based on individual nutritional assessment and in consultation with the participant’s health care provider, as appropriate. Parents and caregivers should be made aware that children’s diets may be nutritionally inadequate when milk is replaced by other foods, and provided appropriate nutrition education. The value of milk for WIC participants, particularly in the development of bone mass for children, should be emphasized. Lactose-free or lactose-reduced fortified dairy products should be offered before non-dairy milk alternatives to those participants with lactose intolerance that cannot drink milk. If milk is replaced by milk
alternatives that are not vitamin D fortified, vitamin D intakes may be inadequate. Thus, replacements for milk are to be approached with caution even if they are rich in calcium.

**Additional Tofu for Women:**
For conditions such as severe lactose intolerance or other qualifying conditions, women may exceed the maximum allowance for tofu substitution with medical documentation up to the maximum allowance for fluid milk. A CPA can determine the need for additional tofu based on an individual assessment and in consultation with a participant’s health care provider, as appropriate.

| VII. Appendix | 2.016A DC WIC Special Formulas/WIC - Eligible Nutritionals by Type of Formula/Medical Food |
| | 2.016B DC WIC Special Formulas/WIC - Eligible Nutritionals Alphabetical Listing |
| | 2.016C DC WIC Prescription and Referral Form |
| | 2.016D Food Packages for Participants with Qualifying Medical Conditions |

| VIII. Reference | 2.012A - Maximum DC CARES Monthly Allowance Special Formula Medical Foods |
| | 2.012B - Food Prescription for Infants |
| | 2.012C - Food Prescription for Women and Children With Special Dietary Needs |
| | 2.013A – DC CARES Default Food Prescriptions for Age and Category |