

PURPOSE: To establish criteria for issuing a food package for qualifying conditions that requires the use of a WIC formula because the use of supplemental foods is precluded, restricted, or inadequate to address their special nutritional needs.

DEFINITIONS:

Children's Special Health Care Services (CSHCS) is a program within Michigan Department of Health and Human Services. It is for children (< 21 years of age) and some adults with special health care needs. CSHCS is a part of Title V of the Federal Social Security Act.

Class I Formula means standard infant formulas produced by the manufacturer awarded the infant formula contract and authorized by the Michigan WIC Program. These are identified as Class I formulas on the list of Michigan WIC Authorized Formulas.

Class II Formula means extensively hydrolyzed exempt infant formulas and non-contract, non-exempt infant formulas authorized by the Michigan WIC Program. These are identified as Class II formulas on the list of Michigan WIC Authorized Formulas.

Class III Formula means all other exempt infant formulas and WIC-eligible nutritionals authorized by the Michigan WIC Program. These are identified as Class III formulas on the list of Michigan WIC Authorized Formulas.

Exempt Infant Formula means infant formula which is represented and labeled for use by an infant with an inborn error of metabolism, low birth weight, or who otherwise has an unusual medical or dietary problem from the requirements of sections 412(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act.

Medicaid is a program that provides healthcare coverage to low-income adults, children, pregnant women, elderly adults, and people with disabilities. Medicaid is administered by states, according to federal requirements.

Qualifying Conditions include but are not limited to preterm birth, failure to thrive, inborn errors of metabolism and metabolic disorders, gastrointestinal disorders, malabsorption syndromes, immune system disorders, severe food allergies that require an elemental diet, and life-threatening disorders, diseases and medical conditions that impair ingestion, digestion, absorption or utilization of nutrients that could adversely affect nutritional status.

WIC-Eligible Nutritionals means enteral products that are specifically formulated and commercially manufactured (as opposed to a naturally occurring foodstuff used in its natural state) to provide nutritional support for individuals with a qualifying condition, when the use of conventional foods is precluded, restricted, or inadequate.

WIC Formula means standard infant formulas, exempt infant formulas, and WIC-eligible nutritionals.

A. POLICY

1. Infants with a qualifying condition may be issued Class II or Class III formulas with medical documentation on DCH-1326, Women, Infants, and Children (WIC) Special Formula/Food Request (See Exhibit 7.03B). For an infant's maximum monthly allowance of formula and supplemental foods, see Policy 7.04, Maximum Food Package, Table B1 and B2 for partially breastfed infants, and Table C1 and C2 for fully formula fed infants.
2. Partially breastfed and fully formula fed infants 6 through 11 months of age, whose medical condition prevents them from consuming supplemental foods, may receive Class I, II, and III formulas at the same maximum monthly allowance as infants 4 through 5 months of age in lieu of supplemental foods.
3. Clients 12 months and older that require the use of a WIC formula and the use of pureed foods may receive infant fruits and vegetables in lieu of the cash-value voucher, and/or infant cereal to replace breakfast cereal with medical documentation on the WIC Special Formula/Food Request. The maximum monthly allowance of infant fruits and vegetables for women is 160 oz, and for children is 128 oz. The maximum monthly allowance of infant cereal is 32 oz for all clients 12 months and older.
4. Clients 12 months and older, except for those exclusively breastfeeding multiple infants from the same pregnancy, may receive a maximum monthly formula package of 910 fl oz. of reconstituted volume in addition to supplemental foods with medical documentation on the WIC Special Formula/Food Request. (See Policy 7.04, Maximum Food Package, Tables D-G).
 - a. Clients exclusively breastfeeding multiple infants from the same pregnancy may receive 1.5 times the maximum monthly formula package of 910 fl oz. of reconstituted volume in addition to supplemental foods. (See 7.04, Maximum Food Package, Table H).
5. Clients 24 months and older with a qualifying condition that requires the use of a WIC formula may receive whole milk in place of low-fat or skim milk with medical documentation on the WIC Special Formula/Food Request.
6. Food packages for qualifying conditions are not authorized 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.
 - b. Infants with a non-specific formula or food intolerance.
 - c. Clients 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.
 - d. Any client solely for the purpose of enhancing nutrient intake or managing body weight without an underlying qualifying condition.

7. Powdered and concentrated formula must be provided whenever possible to contain cost unless the requirements for issuing ready-to-feed (RTF) formula are met as described in Policy 7.02, Authorized WIC Foods. For clients with qualifying conditions and supporting documentation on a WIC Special Formula/Food Request, RTF formula may be assigned for two additional conditions.
 - a. The two additional conditions are:
 - i. If a RTF form better accommodates the client's condition; or
 - ii. If it improves the participant's compliance in consuming the prescribed WIC formula.
 - b. Examples of authorized use of RTF formula for clients with qualifying conditions include, but are not limited to the following:
 - i. Preterm infant discharged from the Neonatal Intensive Care Unit (NICU) with a concern regarding immune function. As powdered formula is not sterile, a physician can prescribe RTF.
 - ii. Fragile infant/child with multiple medical issues which impacts the caregiver. Due to the client's condition, formula must be mixed exactly to maintain osmolality/osmolarity.
 - iii. Medical provider requests return to RTF formula for an infant/child who was previously on RTF and doing well. Infant/child is now refusing to take all alternative forms and weight gain has slowed.
8. Medical Documentation must be written on the WIC Special Formula/Food Request form. Instructions for completing the form can be found in Exhibit 7.03A, DCH-1325, Women, Infants, and Children (WIC) Special Formula/Food Request Instructions.
 - a. Medical determination must be made by a health care provider licensed to write prescriptions under state law.
 - b. A health care provider's prescription form will not be approved in place of the WIC Special Formula/Food Request.
 - c. The WIC Special Formula/Food Request must include:
 - i. Qualifying medical condition(s).
 - ii. WIC formula name, including amount needed per day and duration the formula is prescribed. The duration must not exceed 12 months from the date on the form.
 - iii. When applicable, food restrictions and substitutions, including milk (i.e., whole milk, 2% milk, or soy beverage). See Policy 7.01, Food Package Determination and Customization.
 - iv. Contact information, signature, and date of the health care provider.
 - d. The WIC Special Formula/Food Request must be scanned into the client's record within 2 business days after approval.
 - e. Only when necessary, on an individual participant basis, a telephone order to a Competent Professional Authority (CPA) containing all medical documentation requirements may be used. One month of benefits may be issued, with the expectation that the WIC Special Formula/Food Request must be provided to the local agency within two weeks of benefit issuance.
 - f. The amount of WIC formula and supplemental foods prescribed by a health care provider shall not exceed the federal maximum allowance. (See Policy 7.04, Maximum Food Package).

9. It is the responsibility of the health care provider to provide medical oversight and instruction to clients who are issued supplemental foods that require medical documentation. It is the responsibility of the CPA to ensure appropriate supplemental foods are issued, including substitutions or omissions as indicated by the health care provider (See Policy 7.01, Food Package Determination and Customization.)
10. WIC must coordinate with other federal, state, local government agencies or with private agencies that operate programs that also provide exempt infant formulas and WIC-eligible nutritionals to mutual clients, including at a minimum coordinating annually with the State Medicaid program. WIC may provide up to the maximum allowable amount of WIC formula in situations when formula is not provided by another agency.
 - a. If a WIC client is enrolled in CSHCS or Medicaid, and the formula is one that CSHCS or Medicaid may authorize under certain conditions, WIC should work collaboratively with CSHCS and Medicaid to assure that the nutritional needs of mutual clients are met.
 - b. If a WIC client is enrolled in CSHCS or Medicaid and uses a Class I formula, and also uses a Class II or III formula, arrangements may be coordinated so that WIC provides the Class I formula and CSHCS or Medicaid provides the Class II or III formula.
11. Clients with Inborn Errors of Metabolism:
 - a. If requested by a client or health care provider, nutritional counseling for a client with an inborn error of metabolism must be coordinated with a Children's Hospital of Michigan Metabolic Clinic Registered Dietitian.
 - b. Inborn errors of metabolism include, but are not limited to:
 - i. Galactosemia.
 - ii. Phenylketonuria (PKU).
 - iii. Maple syrup urine disease (MSUD).
 - iv. Methylmalonic acidemia (MMA).
 - c. Contact information for the Children's Hospital of Michigan Metabolic Clinic can be provided by the State Agency upon request.
12. The CPA or Registered Dietitian (RD) is authorized to approve the completed WIC Special Formula/Food Request for a Class I or a Class II formula. This request must be re-evaluated by the CPA or RD.
13. An RD is authorized to approve the completed WIC Special Formula/Food Request for a Class III formula. This request must be re-evaluated by the RD.
 - a. If a local agency does not have an RD available, the CPA must confirm all medical documentation requirements are completed then send the request to the State Agency to be approved or re-evaluated by a State RD.
 - b. Clients receiving Class III formulas must be designated as high risk. (See Policy 5.06, Nutrition Services for High Risk Clients.)
14. All WIC Special Formula/Food Requests that have a duration greater than 6 months must be re-evaluated at approximately the midpoint of the prescription. Re-evaluations must be documented in the client's record to include an assessment of the formula and its use.

Required CPA and RD Approvals/Re-Evaluations for WIC Formulas and Substitutions

WIC Formulas and Substitutions	CPA	Local Agency RD or State RD
Class I Formula (for C1-C4)	X	X
Class II Formula	X	X
Class III Formula		X
Milk substitution (percent fat/soy) with Class I or II Formula (for BE, BP, NPP and C1-C4)	X	X
Milk substitution (percent fat/soy) with Class III Formula (for BE, BP, NPP and C1-C4)		X
Infant foods with Class I or II Formula (for BE, BP, NPP and C1-C4)	X	X
Infant foods with Class III Formula (for BE, BP, NPP and C1-C4)		X

15. Class III Formulas with Special Requirements:

- a. Exempt infant formulas, such as Similac NeoSure and Enfamil NeuroPro Enfacare, may be assigned only to preterm or low birth weight infants who have reached 4 pounds, until catch up growth is complete or until 9 months to 1 year adjusted age.
- b. Alfamino Infant, Elecare Infant, Enfaport, Neocate Infant, Neocate Syneo Infant, and Similac PM 60/40 may be assigned up to 1 year old for full term infants or 1 year adjusted age for preterm infants.
- c. Fortini may be assigned from birth up to 18 months of age or 19.8 pounds.

References:

7 CFR 246.10

21 CFR 107.50

Michigan WIC Authorized Formulas list

American Academy of Pediatrics Committee on Nutrition. Nutritional needs of preterm infants. In: Kleinman RE ed. Pediatric Nutrition Handbook, ed 7, Elk Grove, Ill; American Academy of Pediatrics, 2014:83.

MDHHS, General Information For Families About Children's Special Health Care Services (CSHCS) at: <https://www.michigan.gov/mdhhs/assistance-programs/cshcs/general-information-for-families-about-cshcs>.

Medicaid, Centers for Medicare and Medicaid Services at: <https://www.medicaid.gov/medicaid/index.html>.

Cross References:

- 5.06 Nutrition Services for High Risk Clients
 7.01 Food Package Determination and Customization
 7.02 Authorized WIC Foods
 7.04 Maximum Food Package

Exhibits:

- 7.03A DCH-1325, Women, Infants, and Children (WIC) Formula/Food Request Instructions
 7.03B DCH-1326, Women, Infants, and Children (WIC) Special Formula/Food Request