

7.0 Food Package

Effective Date: 09/09/2020

7.03 Food Package for Qualifying Conditions

PURPOSE: To establish criteria for issuing a food package for qualifying conditions that requires the use of standard WIC infant formulas, exempt infant formulas or WIC-eligible nutritionals, 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 all infant formulas, except exempt 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 under the Contract Formulas section of Michigan WIC Authorized Formulas.

Class II Formula means extensively hydrolyzed exempt infant formulas authorized by the Michigan WIC Program. These are identified as Class II formulas under the Special Formulas section 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 under the Special Formulas section 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 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 formula, exempt infant formula, and WIC-eligible nutritionals.

A. POLICY

1. Infants with a qualifying condition may be issued exempt infant formulas or WIC-eligible nutritionals with medical documentation on the Special Formula/Food Request (DCH-1326). 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. Fully formula fed and partially breastfed 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. This would be in lieu of receiving 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 infant cereal to replace breakfast cereal with medical documentation on the Special Formula/Food Request (DCH-1326). 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 women and children.
4. Pregnant, postpartum and breastfeeding clients, 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. (See Policy 7.04, Maximum Food Package, Table E-G).
5. 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).
6. Children may receive the maximum monthly formula package of 910 fl oz. of reconstituted volume per month in addition to supplemental foods. (See Policy 7.04, Maximum Food Package, Table D).
7. 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 Special Formula/Food Request (DCH-1326).
8. 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.

9. 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. In addition to Policy 7.02, there are two additional conditions which may be used to issue RTF formula with a Special Formula/Food Request (DCH-1326).
 - a. The two additional conditions are:
 - i. If a ready-to-feed 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.
 - c. Select ready-to-feed formula in the most economical container size to meet the needs of the client.

10. Medical Documentation Requirements:
 - 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 Special Formula/Food Request (DCH-1326).
 - c. Medical documentation must be written on the Special Formula/Food Request (DCH-1326).
 - d. Instructions for completing the Special Formula/Food Request (DCH-1326) can be found in the Exhibit 7.03A, WIC Special Formula/Food Request Instructions (DCH-1325).
 - e. The Special Formula/Food Request (DCH-1326) must include:
 - i. Qualifying medical condition(s).
 - ii. WIC formula, including amount needed per day.
 - iii. Supplemental food(s) authorized for the qualifying condition(s).
 - iv. When applicable, milk substitutions (i.e. whole milk, 2% milk, or soy beverage). See Policy 7.02 Authorized WIC Foods.
 - v. Duration the formula is prescribed.
 - vi. Contact information, signature and date of the health care provider.
 - f. The Special Formula/Food Request (DCH-1326) must not exceed a 6-month duration.
 - g. The Special Formula/Food Request (DCH-1326) must be scanned into the client's record within 2 business days after approval.
 - h. 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 Special Formula/Food Request (DCH-1326) must be provided to the local agency within two weeks of benefit issuance.

- i. 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).

11. 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 that only the supplemental foods recommended by the health care provider are issued.
12. 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.
13. 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 Registered Dietitian (R.D.) can be provided by the State Agency upon request.
14. Approval of Class I and Class II Formulas:
 - a. The CPA is authorized to approve the completed Special Formula/Food Request (DCH-1326) for a Class I or a Class II formula.
 - b. The CPA must enter the expiration date of the formula package in accordance with the duration indicated on the Special Formula/Food Request (DCH-1326).
15. Approval of Class III Formulas:
 - a. A local agency R.D. is authorized to approve the completed Special Formula/Food Request (DCH-1326) for a Class III formula.
 - b. If a local agency does not have a R.D. available, the CPA must confirm all medical documentation requirements are completed then send the request to the State Agency to be approved by a State R.D.
 - c. Clients receiving Class III formulas must be designated as high risk. (See Policy 5.06 Nutrition Services for High Risk Clients).

Required CPA and R.D. Approvals for WIC Formulas and Milk Substitutions

WIC Formulas and Milk Substitutions	CPA Approval	Local Agency Authorized R.D. or State R.D.
Class I Formula	X	X
Class II Formula	X	X
Class III Formula		X
Whole/2% Milk Substitution or Soy Beverage with Class II Formula (for BE, BP, NPP and C2-C4)	X	X
Whole/2% Milk Substitution or Soy Beverage with Class III Formula (for BE, BP, NPP and C2-C4)		X
Infant Foods food package with Class I or II Formula (for BE, BP, NPP and C2-C4)	X	X
Infant Foods food package with Class III Formula (for BE, BP, NPP and C2-C4)		X

16. Class III Formulas with Special Requirements:
- a. Exempt infant formulas, such as Similac NeoSure, and Enfamil NeuroPro Enfacare, are available 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. Similac Special Care 24 and Enfamil Premature 24 cal are available only to preterm or low birth weight infants until the infant reaches a body weight of 8 pounds.
 - c. Enfaport, Elecare Infant, 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.

References:

WIC Federal Regulations: 7 CFR Parts 246.10

Food and Drug Federal Regulations: 21 CFR Parts 107.50

Michigan WIC Authorized Formulas

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. Assistance Programs.” *MDHHS - General Information For Families About Children's Special Health Care Services (CSHCS)*, State of Michigan, 2 Aug. 2019, www.michigan.gov/mdhhs/0,5885,7-339-71547_35698-15087--,00.html.

“Medicaid: About Us.” *Medicaid*, Centers for Medicare and Medicaid Services, <https://www.medicaid.gov/medicaid/index.html>.

Cross References:

5.06 Nutrition Services for High Risk Clients

7.02 Authorized WIC Foods

7.04 Maximum Food Package

7.05 Customized Food Package

Exhibits:

7.03A Instructions for Michigan WIC Special Formula/Food Request (DCH-1325)

7.03B Michigan WIC Special Formula/Food Request (DCH-1326)