



SECTION: Nutrition Services 760
SUBJECT: MEDICAL FORMULAS AND NUTRITIONALS
DATE: October 13, 2016 (*Revised*)

POLICY: Local WIC programs are able to issue approved medical formulas and nutritionals to infants, children and women based upon qualifying medical conditions and receipt of medical documentation from a healthcare provider.

PURPOSE: To meet the nutritional needs of infants for whom breastfeeding is not appropriate or possible and whose medical condition contraindicates the use of a standard infant formula, or to meet the nutritional needs of children and women with a documented qualifying medical condition which requires the use of a WIC-eligible medical formula and nutritional because the use of conventional foods is precluded, restricted or inadequate to address their special nutritional needs.

RELEVANT REGULATIONS: 7 CFR §246.10 ¶(c)(1)—Amount and type of eligible infant formulas
7 CFR §246.10 ¶(c)(1)(iii)—WIC formulas requiring medical documentation
7 CFR §246.4—WIC-eligible Nutritionals

OREGON WIC PPM REFERENCES: ♦420—Approval Process for Local Program Policies and Procedures
♦511—Food Benefit Issuance
♦660—Competent Professional Authority: Requirements
♦661—Competent Professional Authority: High-Risk Counseling
♦720—General Information on Formula Use
♦730—Bid Formula: Use and Description
♦733—Formula Warehouse
♦765—Medical Documentation
♦769—WIC Food Packages

APPENDICES: Appendix A 760.6 Qualifying Conditions for Issuance of WIC-Approved Medical Formulas and Nutritionals

DEFINITIONS: *CPA* Competent Professional Authority. An individual on the staff of the local program authorized to determine nutritional risk and prescribe supplemental foods.

Medical formula A formula in which the composition meets the special nutrient requirements of infants, children or adults diagnosed with various medical diseases and conditions. For infants, the medical formula may not meet the complete nutrient specifications defined by the FDA in the Infant Formula Act. Also known by the regulatory term, “exempt infant formula.”

Enteral products that are specifically formulated to provide nutrition support for children over 1 year of age and women with a diagnosed medical condition, when the use of conventional foods is precluded, restricted, or inadequate. Also known as WIC-eligible medical foods. Nutritionals

MEDICAL FORMULAS AND NUTRITIONALS, *cont.*

may be nutritionally complete or incomplete (e.g. Duocal). They must serve the purpose of a food, provide a source of calories and one or more nutrients, and be designed for enteral digestion via oral or tube feeding.

Preterm

A birth occurring at less than 37 weeks gestation and is used synonymously with premature.

Premature infant formula

Infant formula containing more calories per fluid ounce and greater concentrations of protein; vitamins A, C, D, and K; folate; calcium; phosphorus; magnesium; and zinc than standard infant formulas, and that is appropriate to meet the needs of very low birth weight premature infants (birth weight <2000grams). Not indicated for use for full term infants due to risk of hypervitaminosis and/or hypercalcemia. Of the two classifications of premature formulas; in-hospital and post-discharge, only the post-discharge premature infant formulas are eligible for use in WIC.

Standard infant formula

A formula for infants that meets the nutrient specifications defined in the Infant Formula Act. These formulas meet the nutritional needs of healthy, term infants from birth to one year of age. Standard formula is also called “term formula”, “regular infant formula” and “non-exempt” formulas.

WIC Medical Documentation Form

Documentation which includes the federal technical requirements to ensure a licensed health care professional authorized to write medical prescriptions under Oregon law has determined a medical condition/diagnosis which requires the use of a medical formula, nutritional and changes to the participant’s supplemental food package. This form is a request for provision, not a prescription and it replaces prescriptions from health care providers;

PROCEDURE:

Qualifying Condition

1.0 To receive a WIC approved medical formula or nutritional, participants must have one or more qualifying medical conditions as determined by a health care provider licensed to write medical prescriptions in the State of Oregon.

1.1 Refer to Appendix A for qualifying medical conditions warranting use of medical formulas or nutritionals.

Medical documentation

2.0 Medical documentation is required for all medical formulas, nutritionals and infant formula for children over the age of one year, and category-specific supplemental foods. See ♦765— Medical Documentation for the technical requirements for medical documentation.

MEDICAL FORMULAS AND NUTRITIONALS, cont.

- Medical formulas /nutritionals approved for local issuance** 3.0 The Oregon WIC program determines the state formulary of USDA eligible medical formulas and nutritionals to be issued at the local level.
- 3.1 Medical formulas or nutritionals not on the WIC formulary cannot be provided to WIC participants even with a completed medical documentation form. For information on eligible medical formulas/nutritionals for use in Oregon WIC, refer to http://public.health.oregon.gov/HealthyPeopleFamilies/wic/Documents/med_doc_WIC_formulary.pdf
- Forms of formula* 3.2 Medical formulas are available in three basic forms: powder, concentrate and ready-to-feed. See ♦720—General Information on Formula Use, for indications for use and cost considerations.
- In-hospital formula for premature infants* 3.3 The Oregon WIC program does not issue in-hospital premature infant formula or human milk fortifier.
- Concentrating standard infant formula above 20-calories per ounce* 3.4 Local WIC clinic nutritionists and nurses may provide instructions to caregivers for mixing standard formula to above the normal 20-calorie-per-fluid ounce concentration for infants with qualifying medical diagnoses/conditions when authorized by a health care provider.
- 3.4.1 For information on increasing the caloric density of infant formulas or expressed human milk, see *Breastmilk Fortification and Formula Selection and Modification; Specialized Infant Feeding Guidelines for Healthcare Professionals, 2014, Oregon Pediatric Nutrition Practice Group, Oregon Academy of Nutrition and Dietetics*, located in your local agency or contact your nutrition consultant.
- Nutritional Care** 4.0 The WIC nutritionist shall provide nutritional care for participants needing medical formulas or nutritionals and/or modifications to their WIC supplemental foods. In the absence of the WIC Nutritionist, the WIC health professional shall provide the nutritional care.
- 4.1 The nutritional care includes:
- 4.1.1 Assessment and counseling for the woman, or parent/caretaker of the infant or child,
- 4.1.2 Documenting the care plan in progress notes in TWIST including:
- date of counseling,
 - progress made in resolving nutrition risk,
 - nutrition education and counseling provided,
 - identification of participant behavior change
 - and signing all medical documentation forms.

MEDICAL FORMULAS AND NUTRITIONALS, cont.

(Nutritional Care)

4.1.3 Plan to transition off the medical formula or nutritional or return back to breastfeeding, standard infant formula, and/or WIC approved supplemental foods when applicable.

4.2 The WIC nutritionist or WIC health professional may need to contact the participant's health care provider at the beginning and the expiration of the medical documentation and at recertification. This may be necessary to coordinate nutrition care, to verify and update the medical formula or nutritional information, and to obtain a new authorization, if necessary.

4.3 More frequent contact with the participant and health care provider may be needed to monitor for changes in circumstances, facilitate coordination of care, and provide the most effective nutrition education.

Issuing medical formulas in TWIST

5.0 The TWIST data system will allow issuance of one month of benefits for a medical formula prior to entering the medical documentation. TWIST will not allow formula benefits for future months to be issued without receipt of medical documentation and entering a current authorization for the formula.

CPA assigns food package

5.1 Benefits for medical formula or nutritionals **must** be assigned by a CPA. See ♦660—Competent Professional Authority: Requirements

5.1.1 If a participant is in immediate need of a medical formula or nutritional and there is no CPA available in the local clinic, the clerical staff shall call a state nutrition consultant who will review the food package assignment in TWIST for accuracy and completeness. Clerical staff cannot assign food packages. They may, however, enter the medical documentation information received from the healthcare professional into TWIST.

Issuing fewer than 3 months of benefits

5.2 Local programs may consider issuing fewer than three months of benefits for medical formulas or nutritionals if this is a new authorization and/or the participant has not demonstrated tolerance of the new formula. This limits WIC costs for replacement of expensive medical formulas when a participant is repeatedly changing formulas.

Exceptions to full provision of supplemental foods

6.0 The provision of less than the maximum monthly allowances of supplemental foods to an individual WIC participant is appropriate only when:

6.1 The quantities necessary to supplement another program's contribution to fill a medical prescription would be less than the maximum monthly allowance established by federal regulations.

MEDICAL FORMULAS AND NUTRITIONALS, cont.

- 6.2 Medically or nutritionally warranted (e.g. to eliminate a food due to a food allergy).
- 6.3 A participant refuses the maximum monthly allowance.

Formula Warehouse

- 7.0 The Oregon WIC program contracts with a home health provider as a special formula warehouse vendor to provide special or hard-to-find medical formulas or nutritionals to WIC participants. See ♦733—Formula Warehouse.

Coordination of services

- 8.0 WIC local staff shall coordinate provision of medical formulas and nutritionals with health plans and other programs that prescribe and reimburse for such products to ensure coordination of care and to avoid over-issuance of a formula or nutritional.
 - 8.1 Local agencies are encouraged to coordinate provision of care with their local health providers, including coordination of nutrition services to improve access for participants needing medical formulas or nutritionals.
 - 8.2 Metabolic formulas for Inborn Errors of Metabolism are not issued by Oregon WIC. Participants with a medical diagnosis of Inborn Errors of Metabolism (AKA metabolic disorder) are to be referred to the OHSU metabolic specialty clinic, which will provide their metabolic formula. The WIC nutritionist or healthcare professional will coordinate care with the specialty clinic for provision of WIC supplemental foods appropriate to their diagnosis.
 - 8.3 Oregon WIC does not provide medical formulas for participants fed by tube feedings. Requests for medical formulas provided enterally (e.g. gastrostomy tube, nasogastric tube) are to be referred to the enteral company providing the enteral equipment. The WIC nutritionist or healthcare professional will coordinate care with the healthcare provider, specialty clinic for provision of WIC bid formulas and supplemental foods appropriate to the participant's diagnosis or medical needs.

Formula Assistance Programs

- 9.0 Participants needing a specialized medical formula (e.g. Neocate Infant) who do not qualify for Medicaid or other eligible programs may qualify for assistance from the formula manufacturer to meet their full formula needs. Local agency staff may assist the WIC participant in accessing the manufacturer's formula assistance programs. However, local WIC agencies shall not order formulas directly from a formula manufacturer on behalf of the WIC participant.

Medical equipment, unauthorized

- 10.0 All apparatus or devices (e.g. enteral feeding tubes, bags and pumps) designed to administer formulas are not allowable WIC costs. ★

REFERENCES:

- 1. Abbott Nutrition *Product Handbook*. Columbus, Ohio: Abbott Laboratories. April, 2014 <http://www.abbottnutrition.com>

MEDICAL FORMULAS AND NUTRITIONALS, *cont.*

2. Comprehensive Formula Listing, Texas WIC Program. For the most current listing, go to <https://www.dshs.texas.gov/wichd/nut/pdf/FormularyMedicalReasons2016.pdf>
3. Breastmilk Fortification and Formula Selection and Modification; Specialized Infant Feeding Guidelines for Healthcare Professionals. 2014. Oregon Pediatric Nutrition Practice Group, Oregon Academy of Nutrition and Dietetics: <http://www.eatrightoregon.org/pnpg/>
4. Medicaid Policy release: Providing enteral nutrition services for children with Oregon Health Plan benefits. October 1, 2014: <https://www.oregon.gov/oha/healthplan/Announcements/Providing%20Enteral%20nutrition%20services%20for%20children%20with%20Oregon%20Health%20Plan%20benefits.pdf>

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**Qualifying Conditions for Issuance of WIC-Approved
Medical Formulas and Nutritionals**

Participant category	Qualifying conditions including but not limited to the following:	Non-qualifying conditions:
Infants	<ul style="list-style-type: none"> • Premature birth • Low birth weight • Malnutrition • Inborn errors of metabolism/metabolic disorders • Gastrointestinal disorders • Malabsorption syndromes • Immune system disorders • Severe food allergies requiring an elemental formula • Life threatening disorders, disease and medical conditions that impair ingestion, digestions, absorption, or the utilization of nutrients that could adversely affect the participant’s nutritional status 	<ul style="list-style-type: none"> • Non-specific formula or food intolerance • Diagnosed formula intolerance or food allergy to lactose, sucrose, milk protein or soy protein that does not require use of an exempt infant formula
Children (1-4 years)	<ul style="list-style-type: none"> • Premature birth • Malnutrition • Inborn errors of metabolism/metabolic disorders • Gastrointestinal disorders • Malabsorption syndromes • Immune system disorders • Severe food allergies requiring an elemental formula • Life threatening disorders, disease and medical conditions that impair ingestion, digestions, absorption, or the utilization of nutrients that could adversely affect the participant’s nutritional status 	<ul style="list-style-type: none"> • Food intolerance to lactose or milk protein that can be successfully managed with the use of one of the other WIC food packages • Solely for the purpose of enhancing nutrient intake or managing body weight without an underlying qualifying condition
Women	<ul style="list-style-type: none"> • Inborn errors of metabolism/metabolic disorders • Gastrointestinal disorders • Malabsorption syndromes • Immune system disorders • Severe food allergies requiring an elemental formula • Life threatening disorders, disease and medical conditions that impair ingestion, digestions, absorption, or the utilization of nutrients that could adversely affect the participant’s nutritional status 	<ul style="list-style-type: none"> • Food intolerance to lactose or milk protein that can be successfully managed with the use of one of the other WIC food packages • Solely for the purpose of enhancing nutrient intake or managing body weight without an underlying qualifying condition