

Medical Formula

Introduction

Welcome to the Medical Formula training module. This module was adapted with permission from the Wisconsin WIC program and will mainly focus on medical formulas for infants with special nutritional needs.

Objectives

After completing this module, you will be able to:

- Identify the medical documentation needed to provide medical formulas;
- Differentiate between protein structures found in formulas;
- And list two types of medical formulas and the indications for use.

Medical Formula in WIC

WIC participants with a documented qualifying medical condition may receive a medical formula when the use of standard infant formula or conventional food is precluded, restricted, or inadequate to address their special nutritional needs. See MOM 7.9 for more information. For a detailed listing of medical formulas available through Minnesota WIC, see the Minnesota WIC Medical Formula Amounts Guide.

Medical Documentation

To receive a medical formula through WIC, the following information is needed from the Health Care Provider:

- Qualifying medical condition;
- Name of formula;
- Prescribed amount or maximum amount provided by WIC;
- Length of time required;
- Contraindicated foods, if appropriate;
- And signature of the Health Care Provider.

A medical documentation form is available to facilitate collection of the needed information from the Health Care Provider. In rare cases, a medical prescription written on medical stationary may be used as long as all the necessary information is provided. The medical documentation form is designed to facilitate communication between WIC and the Health Care Provider. Documentation must be from a Health Care Professional licensed to write medical prescriptions under Minnesota state law, which includes: Medical Doctors, Physician's Assistants, Certified Nurse-Midwives, Nurse Practitioners, and Licensed Doctors of Osteopathy.

Evaluation of Medical Documentation

A CPA trained in high risk conditions must assess the request and approve the medical documentation form in order for WIC to provide a medical formula. The formula prescribed should be indicated for the medical diagnosis, and the diagnosis must necessitate the need for the formula. For example, if the diagnosis is listed as “fussiness”, this is not an adequate diagnosis and more information would be needed to make a determination if a medical formula is warranted.

If additional information or clarification is needed, the High Risk CPA should call the healthcare provider directly, note any changes or clarifications on the medical documentation form, and if necessary, get additional written documentation or clarification. It is also important to evaluate the appropriateness of the amount of formula provided. The medical documentation form must be scanned into the WIC Information System, and a detailed Individual Nutrition Care Plan, or INCP, must be written.

Follow Up Education

Whenever a medical formula documentation is received, it is critical that formula preparation is discussed with the caregivers to assure that the formula is being prepared in a sanitary manner and as prescribed by the doctor. This should occur at the appointment in which the formula is issued as well as when checking in with the caregiver at subsequent appointments.

The INCP should outline how often WIC will follow up with the participant. Some things to consider when writing an INCP and deciding on the frequency of follow-up include:

- Medical diagnosis;
- Current growth status and/or growth pattern;
- Other healthcare providers following;
- And, understanding of the caretaker.

Medical Documentation Renewal

A new medical documentation form is needed in the following cases:

- If a different medical formula than was initially prescribed is needed;
- If the length of time specified on the medical documentation form has expired, or every six months, whichever is shorter;
- And finally, new documentation is required whenever the food package changes, which occurs at six months and one year of age, because it is necessary to consult with the Health Care Provider on whether it is appropriate to add complementary foods.

For more information on medical documentation and high-risk conditions, refer to MOM 7.6.

Ordering Medical Formula

Consult your agency's WIC Coordinator for specific information on which medical formulas are available locally, either on the grocery shelf or ordered through a pharmacy, and which must be ordered from the State WIC office.

For information on ordering medical formula through the State WIC Office, view the Medical Formula Order Form linked on the slide.

The Direct Ship procedure is used in the WIC Information System to document issuance of any on-hand formula without issuing actual benefits. This procedure should be used for formula ordered through the State WIC Office. See the Direct Ship training module, located in the Information System section of the Local Agency Training, for more information.

Types of Medical Formulas

The most commonly used medical formulas for infants can be broken down into two categories: formula with protein modifications, which include hydrolyzed protein and elemental formulas, and formula for preterm infants. We'll start by taking a closer look at formulas with protein modification.

Protein Modification

Let's look at what occurs when the protein in formula is modified.

Proteins are modified to produce smaller peptides and free amino acids. This is accomplished through a process called hydrolysis. This class of formula can be either partially or extensively hydrolyzed. The protein source may include either whey or casein protein in varying proportions.

While partial hydrolysis helps with digestive tolerance, an allergic reaction may still be triggered with formulas that are only partially hydrolyzed and thus still contain peptide chains. Extensively hydrolyzed formula contains only short-chain peptides, which are much shorter in length than intact protein or partially hydrolyzed protein chains.

The most extensively hydrolyzed formula breaks the protein chain into single amino acids. The result is a formula that does not contain any peptide chains and is called an elemental formula. It may also be referred to as a free amino acid-based infant formula. The smaller the protein particle, the easier it will be to digest and, therefore, less likely to cause an allergic reaction. Extensively hydrolyzed and free amino acid-based infant formulas have been demonstrated to be tolerated by at least 90 percent of infants with documented protein allergies.

Let's take a closer look at the various formulas with each of these protein modifications.

Standard Contract Formulas

Standard contract formula contains intact protein. Enfamil Infant has intact protein from cow's milk, and Similac Soy Isomil has intact protein from soy isolate.

Partially Hydrolyzed Formulas

Enfamil Gentlease and Enfamil Reguline are examples of formulas containing partially hydrolyzed proteins. They are marketed as being more easily digested. Partially hydrolyzed infant formulas are not hypoallergenic and are contraindicated for infants with documented cow's milk protein allergy since they still contain peptide chains.

Extensively Hydrolyzed Formula

The most common extensively hydrolyzed formulas provided by Minnesota WIC are Alimentum, from Abbott Nutrition, and Nutramigen, from Mead Johnson. Although these are both extensively hydrolyzed formulas, they each have a unique composition of macronutrients which may make one hydrolysate formula better suited than another for specific health conditions.

Protein hydrolysate formulas utilize either whey or casein protein. All casein hydrolysate formulas, such as Alimentum and Nutramigen, are lactose free.

Carbohydrate sources in different formulas include corn maltodextrin, sucrose, corn syrup solids, and modified corn starch. The carbohydrate source may vary between different forms of a formula and is important to consider if certain allergies are present. For example, powdered Alimentum contains corn syrup solids but ready-to-feed Alimentum does not contain corn products, so may be appropriate for an infant with a corn allergy.

The fats in hydrolysate formulas are also important to note. Some hydrolysate formulas contain medium-chain triglycerides as the major fat source. "Medium-chain" refers to the length of the fat molecule. Medium-chain triglyceride oils are easier to digest and absorb than fats with longer chain lengths, such as corn, soy, or safflower oils. Infants and children who have a difficult time digesting and absorbing longer chain fats may benefit from formulas with medium-chain triglycerides. Nutramigen is a protein hydrolysate formula that contains only long-chain triglycerides, whereas Alimentum contains 33% medium-chain triglycerides, with the balance being long-chain triglycerides.

Extensively Hydrolyzed Formula cont.

Indications for use of extensively hydrolyzed formulas include:

- Allergies to cow's milk protein and soy protein;
- Gastroesophageal reflux disease (GERD);
- Severe protein calorie malnutrition;
- Malabsorption;
- And galactosemia.

Infants with documented intestinal damage due to cow's milk protein allergy are often equally sensitive to soy protein and should not be given soy formula. Instead, they are usually provided with an extensively hydrolyzed casein formula.

Infants with significant malabsorption are often prescribed extensively hydrolyzed formulas. Formulas that contain a higher percentage of medium-chain triglycerides can be useful for conditions such as short bowel syndrome or bowel resection, pancreatic insufficiency, liver disease, and cystic fibrosis.

There is no evidence to support the use of casein hydrolysate formulas in the treatment of colic, sleeplessness, or irritability.

Extensively Hydrolyzed Formula cont.

Please take a few moments to review information about Alimentum and Nutramigen, linked on the slide. When ready, advance to the next slide.

Amino Acid-Based Elemental Formula

The amino acid-based, or elemental formulas, most commonly provided are Neocate from Nutricia and EleCare from Abbott Nutrition.

The protein source of an amino acid-based formula is 100% single amino acids and contains no lactose. The main carbohydrate source is corn syrup solids. Approximately 33% of the fat in amino acid-based formulas are medium-chain triglycerides to aid in absorption, with the remaining fat source being other vegetable oils.

Amino Acid-Based Elemental Formula: Indications for Use

Infants who have severe protein allergies and have an allergic response to the shorter peptide components in extensively hydrolyzed formulas will usually be provided amino acid-based formula. The proteins in amino acid-based formulas are broken down to elemental, single amino acids so that they can be easily absorbed and digested.

Indications for use of amino acid-based elemental formulas include:

- Allergies to cow's milk protein and soy protein;
- Multiple food protein intolerances;
- Skin, respiratory, and/or gastrointestinal (GI) symptoms caused by food protein allergy;
- Gastroesophageal reflux disease (GERD) caused by food protein allergy;
- Short bowel syndrome;
- Malabsorption;
- And other GI disorders, such as eosinophilic esophagitis.

Parents may complain about the smell of elemental formulas and worry their infant will not like them. The presence of specific aromatic amino acids result in these formulas having a bitter taste. Despite the taste, these formulas are generally well accepted when introduced in the early months, before an infant's sense of taste is well developed.

Amino Acid-Based Elemental Formulas

Take a few minutes and visit the manufacturer's websites linked on the slide to read and learn more about Neocate and EleCare. Advance to the next slide when you are ready.

Formula for Preterm Infants

Infants who are born prematurely are at risk for nutritional deficiencies due to decreased body stores of nutrients at birth and increased demands for growth. Most of the infant's energy, protein, mineral, and other nutrient reserves are stored during the last trimester.

Formula for In-Hospital Use for Preterm Infants

Prior to hospital discharge, premature infants may receive formula designed for in-hospital use only that is higher in certain nutrients, calories, and protein compared to standard formulas. These formulas are designed to help the infant attain growth and bone mineralization close to what they would have, had they not been born early.

Due to infants being discharged earlier than in the past, they are sometimes discharged on these in-hospital use formulas. WIC is able to provide these formulas with medical documentation. They typically come in 2-ounce nursettes, and some examples are Similac Special Care and Enfamil Premature series. Generally, these formulas are discontinued by the time the infant reaches eight pounds since they carry significant risk of providing excessive amounts of some nutrients as the infant takes larger volumes.

These formulas should only be approved for one month at a time. Communication with the Health Care Provider is critical to assure that infants are not left on these formulas too long.

Preterm Infant Formula

Discharged premature infants may continue to have increased nutrient needs and may continue to have trouble digesting and absorbing nutrients. To help with this, formulas for premature infants have modified carbohydrates and fats that are more easily absorbed. These formulas have 22 calories per ounce, compared to the standard formulas that have 20 calories per ounce. They also contain higher amounts of calcium and phosphorous to ensure better bone mineralization, which can continue to be a concern for premature infants.

It is important to note that while it may be appropriate in certain situations to concentrate standard infant formula for term infants to a higher calorie level, it is not the same as a formula designed for the preterm infant. Concentrating of formula should only be prescribed by a Health Care Provider.

There are no definitive guidelines for when to discontinue preterm formula. Birth weight, rate of weight gain, developmental status, and medical conditions are considered when deciding the appropriate time to discontinue use and transition to another formula. Some infants may be prescribed a preterm discharge formula until 9-12 months corrected gestational age.

The most common formulas prescribed for preterm infants are Similac NeoSure and Enfamil EnfaCare. Both can be provided by WIC with medical documentation. Some infants, especially if discharged before 40 weeks gestational age, may benefit from short-term use of ready-to-feed formula due to medical fragility or prematurity putting the infant at risk of *Chronobacter* infection. See MOM 7.5.2 on appropriate use of ready-to-feed formulas. Similac NeoSure and Enfamil EnfaCare may also be used for the fortification of human milk for premature infants.

Please take a few moments to review information about NeoSure and EnfaCare, linked on the slide, before continuing to the next slide.

Solid Foods

Infants who physically cannot take solid foods by six months or later may receive a greater amount of formula from WIC. Some examples of conditions in which this might occur include very premature infants who are not yet at six months-corrected-gestational-age and those with developmental issues preventing them from eating. This also applies to contract formula. Medical documentation stating that the infant cannot take solids is required before the additional formula can be issued. These infants are considered high-risk and require an INCP and INCP follow-up.

Formula beyond One Year

Medical formulas covered in this module may be indicated for children over one year of age. These formulas can continue to be provided with appropriate medical diagnoses and Health Care Provider medical documentation. If standard contract formula is indicated for a child beyond one year of age, medical documentation is also needed. New documentation, regardless of when the last documentation was received, is needed when the baby turns one year because the WIC food package changes, and the Health Care Provider may indicate that certain foods should not be provided.

Pediasure

Pediasure is the most common medical food requested for children over one year of age. In order to issue Pediasure, there must be a medical diagnosis stated on the medical documentation form that indicates Pediasure may be appropriate.

Pediasure, and other similar products, may be appropriate for toddlers or preschoolers with oral motor feeding disorders, tube feedings, failure-to-thrive from an underlying medical condition, or a medical condition that increases calorie requirements beyond what is expected for the child's age. Some conditions associated with increased caloric need include cystic fibrosis, cancer, and congenital heart disease.

Pediasure cont.

It is not unusual for WIC to receive medical documentation for Pediasure that is not warranted. It is often requested because of parental concern about a child's eating habits; parents may think Pediasure is a solution to picky eating or a way to prevent frequent colds.

If medical documentation for Pediasure is received with a diagnosis such as “poor appetite”, “poor growth”, or other vague language, it is not an adequate diagnosis. The CPA should carefully evaluate the child’s growth pattern and discuss and assess appetite, feeding patterns, and other medical concerns with the parent, and if appropriate, with the Health Care Provider. The CPA may deny a request for medical formula or medical food if, in her professional judgement, there is no justifiable need. Document the reason the request was denied in the WIC Information System, including factors considered in making this decision. See MOM 7.6 and 7.9 for more information.

Pediasure Commercials

Why is it so common to have caregivers request Pediasure for their toddlers or preschoolers? Part of the reason and the challenge is that Abbott Nutrition, the company that makes Pediasure, highly advertises its use, targeting parents of preschoolers. Listen to the three sample advertisements linked on the slide. What common concerns from parents of preschool were addressed in the advertisement? How did Pediasure sell their product as the solution to these concerns to parents? When ready, advance to the next slide.

Addressing Concerns

Think about the Pediasure commercials and how these might influence parents. When discussing with parents, focus on their motivation for wanting Pediasure, and discuss factors that may contribute to their concerns.

If an assessment determines that Pediasure is not needed, what conversations might you have with the parent to address their concerns about their child’s growth or eating? Write some key things you might talk about with a worried parent in the box.

Addressing Concerns cont.

What did you write?

Explaining their child’s growth chart can help relieve parents’ worries about how their child is growing. Did you notice how the first Pediasure commercial made the parent think that her child should be as tall as every other child? But the parent herself was very tiny and petite and of Asian descent, so this preschooler is not necessarily behind on his growth, but just growing at his own pace for his genetic makeup.

Assessing fluid intake and how it relates to appetite is something that can help parents understand what is normal. If a child is drinking large quantities of milk or juice, it can affect their appetite. If the child is still using a bottle, this may exacerbate the problem.

Discuss feeding responsibilities with the parent. The parent’s job is to offer a variety of foods at scheduled meal and snack times, and the child’s job is to decide what to eat and how much to eat. Whether toddlers and preschoolers sit down with adults at scheduled meal times may affect how a child

eats. Also, many caretakers do not understand normal portion sizes for toddlers and preschoolers, so they perceive that their child is not eating enough.

When there is disordered eating or disordered mealtimes, if the caregiver is motivated to change, help caregivers set realistic goals to work towards improving their child's eating. Check in with them at their next appointment to see how things are going.

These are just a few things you may have included as things to address with parents. What is discussed will depend on the exact concerns of the parents. Keep in mind your participant centered skills when talking with worried parents, affirming their feelings. Emphasize meeting their needs with what you can provide if it is not appropriate to provide Pediasure. Focus on the shared goal of progressing to typical eating, whether you are providing Pediasure or not. These approaches can help reduce anger and frustration of parents.

End

This concludes the Medical Formula training module. Thank you for your attention.