



State of California—Health and Human Services Agency
Department of Health Care Services



ARNOLD SCHWARZENEGGER
Governor

DATE: November 6, 2007

MMCD Policy Letter 07-016

TO: ALL MEDI-CAL MANAGED CARE HEALTH PLANS

SUBJECT: THERAPEUTIC ENTERAL FORMULAS FOR MEDICAL CONDITIONS IN INFANTS AND CHILDREN (Revised) MMCD Policy Letter 07006 dated April 2, 2007

Purpose

Medi-Cal Managed Care Division (MMCD) Policy Letter 07006, dated April 2, 2007, clarified contractual requirements for Medi-Cal managed care health plans for providing medically necessary therapeutic enteral formulas as a covered Medi-Cal benefit for infants and children below 12 years of age. This revised Policy Letter includes regulatory and contractual timelines for the approval of medically necessary enteral therapeutic formulas. Revisions to Policy Letter 07006 are underlined and italicized.

Background

The Federal Food, Drug, and Cosmetic Act defines infant formula as “a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk” (21 United States Code (U.S.C.) 321(z)). Infant formula is intended to meet the normal needs of healthy infants as a regular food for infants, and as of June 1, 2006, is no longer a covered benefit of the California Children’s Services (CCS) program, Genetically Handicapped Person’s program (GHPP), or Medi-Cal program. The Department of Health Care Services’ (DHCS) Medi-Cal pharmacy benefit excludes coverage of enteral nutrition supplements or replacements, with one exception. Enteral nutrition supplements or replacements are covered when used as a medically necessary “therapeutic regimen to prevent serious disability or death in patients with medically diagnosed conditions that preclude the full use of regular food” (22 California Code of Regulations (CCR) 51313.3(e)(2)).

A therapeutic “medical” food is one that is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation (21 U.S.C. 360ee(b)(3)). Therapeutic formula feedings used to boost normal growth and development in certain infants and children or to prevent serious disability and death may be administered orally or by means of an enteral feeding tube. The U.S. Food and Drug Administration (FDA) defines “special dietary uses” of foods (21 Code of Federal Regulations (CFR) 105.3 (a)(1)) as:

- i supplying particular dietary needs that exist by reason of a physical, physiological, pathological, or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, and underweight and overweight;
- ii supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood; and
- iii supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property, of which use of any food as such is a special dietary use, regardless of whether such a food also purports to be or is represented for general use.

Standard of Care Policy

Medically Necessary Therapeutic Enteral Formulas

Plans are required to provide or arrange for all medically necessary covered services. This includes all covered services that are reasonable and necessary to protect life, prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness or injury (22 CCR 51303(a)). Plans shall develop and implement written policies and procedures for providing medically necessary therapeutic enteral formulas that address the following:

- Authorization and approval criteria for providing therapeutic enteral formulas based on current sound medical evidence and/or clinical best practice guidelines;
- A system for consistent application of medical necessity criteria for therapeutic enteral formula for specific medical conditions, regular review and updating of criteria, and clear documentation of reasons for decisions;
- A system for providing medically necessary therapeutic enteral formulas and the equipment/supplies necessary for delivery of these special foods;

- A process established by plan and/or in collaboration with local county public health or community agencies to evaluate social and environmental conditions related to Failure to Thrive (FTT) infants and children; and
- An adequate time period, not to exceed 120 days, for new plan members to continue receiving a current therapeutic formula regimen until medical necessity is determined by the new plan.

Requirements for Medical Authorization of Therapeutic Enteral Formulas

- Authorization procedures and review for approval of therapeutic enteral formulas shall be supervised by qualified healthcare professionals, and denials shall be reviewed by a qualified physician;
- Decisions and appeals regarding therapeutic enteral formula shall be performed in a timely manner based on the sensitivity of medical conditions and rendered as:
 - a. Emergency requests: in no event shall prior authorization be required when there is a bona fide emergency requiring immediate treatment (Welfare and Institutions Code Section 14103.6);
 - b. Expedited requests: within three (3) working days for services that a provider or a plan determines that following the standard timeframe could seriously jeopardize the member's life or health or ability to attain, maintain, or regain maximum function;
 - c. Non-emergency requests: within five (5) working days when proposed treatment meets objective medical criteria, and is not contraindicated; and
 - d. Regimen already in place: within five (5) working days for review of a currently provided regimen as consistent with urgency of the member's medical condition (Health and Safety Code Section 1367.01);
- Any decision on therapeutic enteral formula that is delayed beyond these time periods is considered an approval and must be immediately processed as such;
- Verbal or written notification shall be provided to any provider requesting a service by prior authorization that is denied, approved, or modified in an amount, duration or scope that is less than that requested by the provider;
- Members shall be notified about denied, deferred, or modified services; and
- Plans shall publicize the appeals procedure for both providers and members.

Referrals to Women, Infants and Children's (WIC) Program

- Members should **not** be referred to WIC for therapeutic enteral formulas because WIC does not receive funding to supply these products or the accompanying services for ongoing evaluation of medical conditions;

- Only women who are pregnant, breastfeeding, or postpartum, or the parent/guardian of a child less than 5 years of age should be referred to a local WIC agency for food supplement and nutrition education program services, with documentation of the referral made in the member's medical record (42 CFR 431.635(c)); and
- Providers shall also provide a current hemoglobin (Hgb) or hematocrit (Hct) laboratory value for the WIC referral and periodically as needed for ongoing WIC program participation, and document the value in the member's medical record.

Informing Providers and Members

- Plans shall inform providers about authorization procedures for provision of therapeutic enteral formulas, timeliness standards, requirements for periodic physical assessment and follow-up evaluation, local referral resources, formulary list of approved therapeutic formulas, and processes for approval of newly marketed therapeutic enteral formulas; and
- Plans shall inform members about the processes and procedures for provision of medically necessary therapeutic enteral formulas.

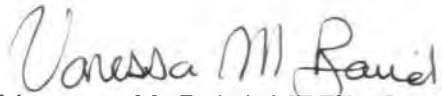
Discussion

Indications for appropriate use of therapeutic formulas include physical, physiologic, or pathologic conditions resulting in inadequate nutrition, inherited metabolic disorders, including but not limited to disorders of carbohydrate, lipid, vitamin, mineral, or amino acid and nitrogen metabolism, and conditions resulting in impairment of oral intake affecting normal development and growth (American Academy of Pediatrics, Policy Statement, *Pediatrics* Vol. 111, No. 5, May 2003).

Determining the medical necessity of therapeutic enteral formulas for medical conditions requires a thorough history, physical examination, nutrition assessment, laboratory testing, feeding observation, and evaluation of parenting behavior and home environment. Malnutrition in children can result in impaired growth and long-term deficits in intellectual, social, and psychological functioning. For this reason, plans are strongly encouraged to work collaboratively with local county and community agencies through the Memorandum of Understanding (MOU) process to evaluate and meet the needs of these high risk health plan members.

We greatly appreciate your attention to these issues. If you have any questions, please contact Dr. Michael Farber, Chief, Medical Policy Section, Medi-Cal Managed Care Division, at (916) 449-5149.

Sincerely,

A handwritten signature in cursive script that reads "Vanessa M. Baird".

Vanessa M. Baird, MPPA, Chief
Medi-Cal Managed Care Division