

State of California—Health and Human Services Agency

Department of Health Care Services



DATE: February 28, 2023

CCS Information Notice: 23-01

TO: All County California Children's Services Program Staff, County Medical

Consultants and Staff, Genetically Handicapped Persons Program Providers and Staff, and Integrated Systems of Care Division Staff

SUBJECT: LOW PROTEIN THERAPEUTIC FOODS (LPTF), FORMALLY KNOWN

AS MEDICAL FOODS

The purpose of this California Children's Services (CCS) Information Notice (IN) is to provide information regarding the Low Protein Therapeutic Foods (LPTF), formally known as Medical Foods, formerly billable by the code Z5999.

A medical food, as defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee (b)(3)), is "a food which 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." Based on this definition, many enteral nutrition manufacturers and Medi-Cal are now referring to most enteral nutrition formulas as "Medical Foods."

Low protein therapeutic foods are a distinct subset of the medical foods defined above. LPTF, formerly described as medical foods by CCS are products that are specially formulated for the treatment of certain inborn errors of metabolism and are requested by registered dieticians in collaboration with center physicians, and then purchased from vendors who specialize in the distribution of low-protein foods. Due to the extended meaning of Medical Foods by the Food and Drug Administration and Medi-Cal, the CCS Program and GHPP will now refer to these products as LPTF.

LPTF identification, prescription and delivery are administered through a collaborative effort between Special Care Center Registered Dieticians (SCC RD), Pharmacy providers, and CCS counties.

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Beginning March 1, 2023, the following will be in effect:

- The term "LPTF" will replace the use of the term "medical foods".
- LPTF will be authorized by a HCPCS code S9435 (Medical foods for inborn errors of metabolism) instead of by Z5999, in the Children's Medical Services Network System (CMS Net).
- Revised LPTF-ROF be used.
- Increased LPTF dollar limit to:
 - o A maximum of \$1,500 per 3 months or \$3,000 per 6 months.
 - Maximum dollar amount indicated should not be taken as a "must spend" maximum dollar amount. While ensuring that clients receive an adequate amount of food to meet their nutritional needs, it is Special Care Center Registered Dietician's responsibility to ensure no item beyond the client's need is ordered.
- In the event <75% of the original order is available to be shipped:
 - Pharmacy should consult with the RD and with the RD's approval, place the order.
 - Secondary order may be placed within two (2) weeks of the first order for alternative products to replace the unavailable items.
 - A secondary SAR request and provisional approved SAR should indicate the reason for the secondary order request.
 - Maximum dollar amount per order cycle does not change (both the first order and secondary order must be within the dollar limits of the order cycle).

LPTF is not a Medi-Cal benefit. SAR should have a prefix 91 for CCS with full scope Medi-Cal with no share of cost clients by checking the EPSDT box when pending the SAR.

If you have any questions regarding this IN, please contact the Integrated Systems of Care Division Medical Policy team, via email at ISCD-MedicalPolicy@dhcs.ca.gov.

Sincerely,

ORIGINAL SIGNED BY

Cortney Maslyn
Division Chief
Integrated Systems of Care Division