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TO: All County California Children's Services Programs Administrators

SUBJECT: Low-Protein Therapeutic Foods as a Benefit for California Children's Services Program and Genetically Handicapped Person's Program Members with Inborn Errors of Metabolism

I. PURPOSE

The purpose of this Numbered Letter (NL) is to update guidance on the medical necessity criteria for low-protein therapeutic foods (LPTF), a type of medical foods, by the California Children's Services (CCS) Program and Genetically Handicapped Person's Program (GHPP).

II. BACKGROUND

A. Inborn errors of metabolism (IEM) are rare genetic or inherited disorders involving impaired function in biochemical pathways that result in a buildup of toxic substances and / or a lack of essential products.¹ Genetic defects in the biosynthesis, degradation or transport of amino acids lead to a diverse

¹ Saudubray JM, Garcia-Cazorla À. Inborn Errors of Metabolism Overview: Pathophysiology, Manifestations, Evaluation, and Management. *Pediatr Clin North Am.* 2018 Apr;65(2):179-208. doi: 10.1016/j.pcl.2017.11.002. PMID: 29502909.

subset of IEM that affect amino acid metabolism.² The majority of individuals with untreated IEMs develop progressive irreversible brain injury resulting from direct toxicity from various toxic metabolites.³ Particularly in infants and children, high amino acid levels can interfere with brain development and function, leading to intellectual disability, behavioral problems, seizures, developmental delays, psychiatric disorders, and skin conditions, such as eczema.⁴ The most common of these IEM is phenylketonuria (PKU); more rare conditions include homocystinuria, maple syrup urine disease and tyrosinemia.

B. IEM Management

Critical to the management of these disorders is early diagnosis and treatment. Since July 1, 2000, California has required every health care service plan contract to provide coverage for the testing and treatment of PKU.⁵ The California Newborn Screening Program tests all newborns for IEM and works with County CCS Programs, managed care plans, and Metabolic Special Care Centers (SCC) to complete confirmatory testing and initiate treatment for affected infants.^{6,7} The CCS Program and GHPP use the statutory standards for PKU special food products as a guide for IEM generally and provide them to CCS Program and GHPP members with any IEM that requires amino acid or protein restriction, and not just to those with PKU.⁸

² Ziegler SG, Kim J, Ehmsen JT, Vernon HJ. Inborn errors of amino acid metabolism - from underlying pathophysiology to therapeutic advances. *Dis Model Mech*. 2023 Nov 1;16(11):dmm050233. doi: 10.1242/dmm.050233. Epub 2023 Nov 23. PMID: 37994477; PMCID: PMC10690057.

³ Gropman AL. Patterns of brain injury in inborn errors of metabolism. *Semin Pediatr Neurol*. 2012 Dec;19(4):203-10. doi: 10.1016/j.spen.2012.09.007. PMID: 23245553; PMCID: PMC3758694.

⁴ Rice GM, Steiner RD. Inborn Errors of Metabolism (Metabolic Disorders). *Pediatr Rev*. 2016 Jan;37(1):3-15; quiz 16-7, 47. doi: 10.1542/pir.2014-0122. PMID: 26729777.

⁵ California Code, Health and Safety Code - HSC § 1374.56(a)

⁶ [Newborn Screening Program, California Department of Public Health](#)

⁷ Kemper AR, Boyle CA, Brosco JP, Grosse SD. Ensuring the Life-Span Benefits of Newborn Screening. *Pediatrics*. 2019 Dec;144(6):e20190904. doi: 10.1542/peds.2019-0904. Epub 2019 Nov 6. PMID: 31694980; PMCID: PMC7202673.

⁸ California Code, Health and Safety Code - HSC § 1374.56(a)

These diseases have highly complex underlying pathophysiology, biochemical workup, molecular analysis, and therapeutic options for management.⁹ The mainstays of treatment involve dietary modifications that restrict natural protein intake in favor of low-protein foods and supplementation with essential amino acids and medical foods specifically designed to avoid accumulation of toxic substrates, achieve metabolic control, support growth and development, and prevent adverse outcomes.¹⁰ There is strong evidence to support the position that treatment and maintenance of metabolic control throughout life is essential to optimal functioning of individuals with IEM.¹¹ Aggressive treatment during infancy and childhood prevents intellectual disability and continuation of nutritional interventions during adolescence and adulthood has been shown to mitigate a variety of adverse neurocognitive and psychiatric outcomes.¹²

C. Medical Foods

The U.S. Food and Drug Administration (FDA) defines a medical food as “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”.¹³

Although medical foods are ordered by medical physicians for management of a disease, they are not drugs and are not subject to FDA pharmaceutical

⁹ Agana M, Frueh J, Kamboj M, Patel DR, Kanungo S. Common metabolic disorder (inborn errors of metabolism) concerns in primary care practice. *Ann Transl Med.* 2018 Dec;6(24):469. doi: 10.21037/atm.2018.12.34. PMID: 30740400; PMCID: PMC6331353.

¹⁰ Berry SA, Brown CS, Greene C, et al. Medical Foods for Inborn Errors of Metabolism: History, Current Status, and Critical Need. *Pediatrics.* 2020;145(3):e20192261. doi:10.1542/peds.2019-2261doi:10.1038/gim.2013.15

¹¹ Kruszka P, Regier D. Inborn Errors of Metabolism: From Preconception to Adulthood. *Am Fam Physician.* 2019 Jan 1;99(1):25-32. PMID: 30600976.

¹² Vockley J, Andersson HC, Antshel KM, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. *Genet Med.* 2014;16(2):188-200.

¹³ [Section 5\(b\)\(3\) of the Orphan Drug Act \(21 U.S.C. § 360ee \(b\)\(3\)\)](#)

regulation.¹⁴ Instead, they are regulated as food and subject to food labeling requirements that include identity statements, quantity of contents, complete list of ingredients and manufacturer's name and location.¹⁵ They are not required to provide nutrition labeling, health claim, or nutrient disclosure under the Nutrition Labeling and Education Act of 1990.¹⁶

- D. California statute requires that health care service plans, which include all Knox-Keene licensed Medi-Cal Managed Care Plans (MCPs) cover testing and treatment for PKU including formulas and special food products that are part of a diet prescribed by a licensed physician who specializes in the treatment of metabolic disease, provided that the diet is deemed medically necessary to avert the development of serious physical or mental disabilities or to promote normal development or function as a consequence of PKU.¹⁷

E. Delivery Systems

1. The Medi-Cal program covers enteral nutrition formula through Medi-Cal Rx as a pharmacy benefit for all covered Medi-Cal members.¹⁸ This includes a robust group of metabolic - and other types - of therapeutic enteral nutrition formula which are used to mitigate a variety of IEM disorders. LPTF enteral nutrition formulas are included in these covered products.
2. Enteral nutrition formula coverage through Medi-Cal Rx requires a prior authorization (PA) demonstrating medical necessity, category criteria requirements, and requires the formula is used as a "therapeutic regimen to prevent serious disability or death in patients with medically diagnosed conditions that preclude the full use of regular food".¹⁹ Coverage is restricted to the Medi-Cal Rx List of Contracted Enteral Nutrition Products

¹⁴ Camp KM, Lloyd-Puryear MA, Huntington KL. Nutritional treatment for inborn errors of metabolism: indications, regulations, and availability of medical foods and dietary supplements using phenylketonuria as an example. *Mol Genet Metab.* 2012;107(1–2):3–9

¹⁵ [Medical Foods Guidance Documents & Regulatory Information](#)

¹⁶ [21 U.S.C.A. § 343\(q\)\(5\)\(A\)](#)

¹⁷ [California Code, Health and Safety Code - HSC § 1374.56\(b\)](#)

¹⁸ [Medi-Cal Rx Provider Manual](#)

¹⁹ W&I Code, Sections 14105.395, 14105.8, and 14132.86

(List), which includes liquid ready-to-feed, reconstitute powder-to-liquid, and blended formulations. Additionally, protein-equivalent tablets are also a covered product, restricted to IEM conditions and contracted products. Regular food and solid, semi-solid, and pureed foods are exempt from coverage by Medi-Cal. For CCS Program and GHPP members with Medi-Cal and Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) beneficiaries, a PA could override Medi-Cal requirements for enteral formula coverage. However, a PA will not approve or override non-liquid forms of any foods for coverage through Medi-Cal Rx.

3. The CCS Program and GHPP provide as medical benefits additional medical foods in other enteral formulations (solid and semi-solid forms) to CCS Program and GHPP members with any IEM that requires amino acid or protein restriction, and not just to those with PKU.^{20,21,22} The following conditions apply for these medical foods for CCS and GHPP members as a covered benefit. The food:
 - a. Must be prescribed consistent with the recommendations and best practices of qualified health professionals with expertise germane to and experience in the treatment and care of these IEM conditions.
 - b. Does not include foods that are naturally low in protein.
 - c. May include food products specially formulated to have less than one gram of protein per serving.
 - d. Are used in place of normal food products, such as grocery foods, used by the general population.

The CCS Program and GHPP refer to these food products as LPTF and provide them as a benefit to individuals with qualifying IEM diagnoses.

²⁰ California Code, Health and Safety Code - HSC § 1374.56(a)

²¹ [California Code, Health and Safety Code - HSC § 1374.56\(d\)\(2\)\(A\)](#)

²² California Code, Health and Safety Code - HSC § 1374.56(a)

III. POLICY

A. Eligibility

LPTF are medically necessary as an EPSDT benefit for those under the age of 21 and broadly medically necessary for the lifelong treatment of individuals with a CCS- or GHPP-eligible IEM diagnosis for which specific nutritional requirements are needed to prevent adverse neurological outcomes.^{23, 24, 25} LPTF that are provided to patients in skilled nursing, intermediate care or hospital facilities are included in the inpatient fees.

B. Metabolic Goals

Metabolic registered dietitian (RD) / physician teams have the expertise to customize individual nutritional plans for patients with IEM based on the severity of the metabolic condition, age, growth, and overall clinical status.²⁶ LPTF are a substitution to a standard food that must be excluded from the patient's diet or consumed in extremely limited quantities depending on their protein tolerance.²⁷ They are modified to be low in protein and to provide needed calories, enhance satiety, and increase diet variety to increase adherence.²⁸

C. Program Benefits

²³ [CCS, 22 CCR § 41515.1 et seq.](#)

²⁴ [GHPP, 17 CCR § 2932](#)

²⁵ California Code, Health and Safety Code - HSC § 1374.56

²⁶ García-Arenas D, Barrau-Martínez B, González-Rodríguez A, Llorach R, Campistol-Plana J, García-Cazorla A, Ormazabal A, Urpi-Sarda M. Effect of Special Low-Protein Foods Consumption in the Dietary Pattern and Biochemical Profile of Patients with Inborn Errors of Protein Metabolism: Application of a Database of Special Low-Protein Foods. *Nutrients*. 2023 Aug 6;15(15):3475.

²⁷ [Advisory Committee on Heritable Disorders in Newborns and Children. Committee Report Medical Foods for Inborn Errors of Metabolism: The Critical Need to Improve Patient Access.](#)

²⁸ Vockley J, Andersson HC, Antshel KM, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. *Genet Med*. 2014;16(2):188-200.

The remainder of this NL focuses on non-liquid LPTF formulations provided as medical benefits by the CCS Program and GHPP.

A wide variety of LPTF medical foods in non-liquid formulations are benefits of the CCS Program and GHPP. These include low-protein grains, breads, pasta, rice, cheese, prepared meals, snacks, and desserts. Diversity in the diet is critical for adherence and helps to normalize the protein-restricted diet.²⁹ Gluten-free, dairy-free, and vegan options may be necessary to meet an individual's medical, cultural, or personal needs.

LPTF are a benefit of the CCS Program and GHPP when **all** of the following conditions are met. LPTF must:

1. Correct or ameliorate an IEM for a CCS member or treat an adult with a GHPP-eligible IEM; and
2. Be used in place of normal food products used by the general population or in addition to or replacing enteral nutrition formula (administered as liquid nutrition);³⁰ and
3. Be specially formulated for the dietary management of an IEM for which specific nutritional requirements exist;³¹ and
4. Not replace a food that is naturally low in or does not contain protein;³² and
5. Be prescribed by a physician who specializes in the treatment of metabolic diseases.³³
 - a. For CCS, LPTF are prescribed by a CCS-paneled physician or nurse practitioner who is a member of a CCS-approved Metabolic SCC for

²⁹ Camp KM, Lloyd-Puryear MA, Huntington KL. Nutritional treatment for inborn errors of metabolism: indications, regulations, and availability of medical foods and dietary supplements using phenylketonuria as an example. *Mol Genet Metab.* 2012 Sep;107(1-2):3-9.

³⁰ [List of Covered Enteral Nutrition Products](#)

³¹ [California Code, Health and Safety Code - HSC § 1374.56\(b\)](#)

³² [California Code, Health and Safety Code - HSC § 1374.56\(d\)\(A\)](#)

³³ [California Code, Health and Safety Code - HSC § 1374.56\(d\)\(2\)\(A\)](#)

members currently receiving comprehensive nutrition services by a CCS-paneled RD.

- b. For GHPP, LPTF are prescribed by a Medi-Cal-enrolled physician or nurse practitioner for members currently receiving comprehensive nutrition services by a Medi-Cal enrolled RD.

IV. POLICY IMPLEMENTATION

Complete details can be found in the CCS and GHPP LPTF Order Processing Manual.³⁴

A. LPTF Requests

1. Classic CCS counties and whole child model (WCM) MCPs adjudicate LPTF requests, with approvals authorized to participating pharmacies enrolled as Medi-Cal program providers.
2. Medi-Cal Rx does not process LPTF requests.

B. Required Documents

1. A prescription dated within twelve months of order placement and signed by a CCS-paneled medical practitioner or a GHPP member's Medi-Cal provider.
2. Low Protein Therapeutic Foods Request and Order Form (LPTF-ROF) Excel Spreadsheet available through ISCD-MedicalPolicy@dhcs.ca.gov. This excel spreadsheet may be used as a prescription if prescriber signs and dates it. However, a prescription does not replace the LPTF-ROF Excel Spreadsheet.
3. Current medical history and evaluations within the last twelve months by the CCS-paneled physician and RD that identify the medical condition and any other pertinent medical records or reports, including:
 - a. The member's anthropometric and biochemical data and other pertinent medical reports to justify the products requested.

³⁴ [CCS and GHPP LPTF Order Processing Manual](#)

- b. A medical nutrition therapy treatment plan that includes planning for formula, foods, and adjunctive treatments.
- c. Confirmation of member compliance with the LPTF diet.

C. Submission Process

1. For Medi-Cal members in CCS classic counties, the provider submits the required documents using the Provider Electronic Data Interchange web portal.³⁵ GHPP receives the required documents by encrypted email.
2. For CCS members in WCM counties, the provider submits the required documents to the MCP.
3. For CCS members with full-scope, no share of cost Medi-Cal, LPTF are requested as an EPSDT benefit.
4. Providers submit LPTF requests for CCS or GHPP members who are state-only to their other health care insurance, if applicable, as the CCS Program and GHPP are the payers of last resort.
5. The LPTF Healthcare Common Procedure Coding System code is S9435 (Medical foods for inborn errors of metabolism). The number of items is the code's units.
6. The provider submits the completed LPTF-ROF to the pharmacy through an encrypted email or fax.

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

³⁵ [CMS Net Provider Electronic Data Interchange \(ca.gov\)](#)

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Sincerely,

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