**TEMPLATE** LETTER OF MEDICAL NECESSITY: PKU cooler**[10, 15, 20]**

DATE:

PATIENT NAME:

DOB:

Ht: Wt:

INSURANCE ID:

GROUP #:

SUBSCRIBER NAME:

ICD DIAGNOSIS CODE:

MEDICAL FOOD ORDER:

HCPCS PROCEDURE CODE:

To Whom It May Concern:

**­­[Patient Name]** is a \_**\_\_\_\_** year old patient diagnosed with phenylketonuria (PKU), an inborn error of metabolism. This patient’s metabolic disease was diagnosed **[through newborn screening (if applicable) which is mandated by law in the USA]** on **[date diagnosed]**. The purpose of this letter is to explain the medical necessity of Vitaflo PKU cooler**[10, 15, 20]** and request insurance coverage for this medical care.

PKU is a life-long inherited metabolic disease, characterized by the body’s inability to utilize the essential amino acid, phenylalanine (Phe). PKU is caused by a deficiency of the enzyme phenylalanine hydroxylase. Due to this enzyme deficiency, the affected individual is unable to metabolize Phe. This leads to an accumulation of Phe in the blood and body tissues. This accumulation is toxic to the central nervous system leading to severe problems, including **[severe neurological complications including intellectual disability].** The accepted standard of care is to eliminate high protein foods, to severely restrict other protein containing foods, and prescribe a medical food formulated to provide amino acids (excluding Phe), vitamins, and minerals in a precise mix to meet the patient’s nutrient needs. The patient requires this Phe-free medical food as their primary source of dietary protein. If this patient doesn’t follow the prescribed strict dietary management accordingly, long term medical consequences ensue.

The patient is prescribed Vitaflo PKU cooler**[10, 15, 20]**, to meet their distinct nutritional needs and ensure that they maintain blood Phe in the recommended target range. Dietary and medical guidelines for the management of PKU by the American College of Medical Genetics and Genomics and Genetic Metabolic Dietitians International recommend maintaining blood Phe between 120-360 µmol/L (2-6 mg/dL) in patients of all ages for life.

PKU cooler**[10, 15, 20]** can be administered orally or tube fed. It is not an over the counter product**.** PKU cooler**[10, 15, 20]** is a medical food, which is classified as an enteral formula according to the Healthcare Common Procedure Coding System (HCPCS). HCPCS Codes are B4157 & B4162. **[Reimbursement Codes for PKU cooler10 are: 12539-0020-36 (red flavor).]**  **[Reimbursement Codes for PKU cooler15 are: 12539-0020-40 (orange flavor); 12539-0020-43 (purple flavor); 12539-0020-37 (red flavor).]** **[Reimbursement Codes for PKU cooler20 are: 12539-0020-41 (orange flavor); 12539-0020-44 (purple flavor); 12539-0020-38 (red flavor)].** It is manufactured for Vitaflo USA, LLC (Tax ID 14-1886053).

Please approve coverage of this prescribed medical food/enteral formula for this patient’s inborn error of metabolism. Consideration of this request is appreciated. Please contact me if you have additional questions.

Sincerely,

Name of Physician

NPI#

Institution

Contact Information

Attachments: Prescription and Clinic Notes