

**TEMPLATE LETTER OF MEDICAL NECESSITY: PKU AIR20**

DATE:

PATIENT NAME:

DOB:

Ht:      feet      inches      Wt:

INSURANCE ID:

GROUP #:

SUBSCRIBER NAME:

ICD DIAGNOSIS CODE:

MEDICAL FOOD ORDER:

HCPCS PROCEDURE CODE:

To Whom It May Concern:

\_\_\_\_\_ 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 \_\_\_\_\_. The purpose of this letter is to explain the medical necessity of Vitaflo PKU Air20 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 PKU Air20, a medical food formulated to meet the specialized nutritional needs of patients with PKU fed orally or enterally. The prescribed medical food is imperative in the dietary management of this patient's condition and medically necessary to ensure that **[he/she]** maintains 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 Air20 is a medical food, which is classified as an Enteral Formula according to the Procedure Code (HCPCS Code). HCPCS Codes are B4157 & B4162. Reimbursement codes are: 50600-0216-98 (gold flavor); 50600-0217-04 (green flavor); 50600-0217-11 (yellow flavor). PKU Air20 is manufactured in the UK for Vitaflo USA, LLC (Tax ID 14-1886053.)

I appreciate your consideration of this request. Your authorization of this prescribed order will provide this patient the diet management needed to improve his/her medical situation.

Please feel free to contact me if you have additional questions.

Sincerely,

Name of Physician:

NPI#

Institution

Contact Information

Attachments: Prescription and Clinic Notes