**Letter of Medical Necessity for Medical Food/Formula**

[Date] RE: [Patient name]

D.O.B: [Patient date of birth]

To Whom It May Concern:

We are writing a letter of medical necessity regarding the management of [patient name] who is under the medical care of [clinic name]. [Patient name] was born with a genetic disorder, phenylketonuria (PKU) (ICD-10 E70.0), which is an inborn error of metabolism. We are writing to request that the medical food/formula, PKU GOLIKE be covered by [his/her/their] current medical insurance, as it is medically necessary for the management of [his/her/their] PKU. Other medical history includes [ ].

PKU is a life-long disease, characterized by the body’s inability to metabolize the essential amino acid, phenylalanine (Phe). PKU is caused by a deficiency of the enzyme phenylalanine hydroxylase (PAH). If left untreated, the accumulation of Phe in the blood is toxic to the central nervous system leading to severe neurological complications, including intellectual disability. The accepted standard of care is dietary restriction of natural protein while consuming a Phe-free medical food that provides the amino acids and other nutrients required for proper growth and development.

Currently, [patient’s name] is prescribed [name of product], which is a medical food/formula used to manage PKU to serve as the primary source of protein and micronutrients. PKU GOLIKE is fed orally and prescribed based on age and protein needs. It is not an over-the-counter product and must be used under medical supervision. If this patient does not follow the prescribed strict dietary management accordingly, irreversible long term medical consequences ensue.

The prescribed medical food, PKU GOLIKE, is imperative in the management of this patient’s condition and medically necessary to ensure that they maintain blood Phe in the recommended target range. PKU GOLIKE’s prolonged release granules allows for a more physiological absorption of amino acids that may help patients achieve better metabolic control. 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.

We appreciate your attention to this request for [patient’s name]’s medical food/formula, PKU GOLIKE, to be covered by [his/her/their] current medical insurance. Please do not hesitate to contact us if you have any questions at [clinic contact information].

[Clinician/Dietitian name], [credentials]

[Physician name], [physician credentials], [clinic name]

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