**Letter of Medical Necessity**

Date:

Insurance Company:

Member ID:

Patient Name:

DOB:

Medical Condition: Phenylketonuria (PKU) ICD-10 E70.0

CPT/HCPCS Code: S9435,B9998

To Whom It May Concern:

We are writing this letter of medical necessity regarding the medical treatment of Patient name who is under the medical care of (insert clinic). Patient was born with a genetic disorder, Phenylketonuria (PKU)(ICD-10 E70.0), which is an inborn error of metabolism. We are requesting the medical formula PKU GOLIKE be covered by (pt name) current insurance as it is medically necessary for the treatment of PKU.

PKU is an incurable, lifelong disease where the amino acid phenylalanine(phe) cannot be metabolized by the body. This leads to increased levels in Phe in the blood which becomes toxic to the central nervous system leading to severe neurologic consequences including cognitive disability, seizures, and even death. The standard of care for PKU is dietary restriction of natural protein while also consuming a no phe medical formula that provides amino acids necessary for proper growth and development.

PKU GOLIKE (bars or granules) has physiomimic technology that releases amino acids slowly much like that of natural proteins. Its special coating also conceals any adverse taste issues, bloating, and bad breath that often arise with other PKU Formulas. The delayed release can lead to prolonged satiety and does not need to be consumed with large volumes of liquid (Anita MacDonald\*, 2020). Patients on PKU GOLIKE may help achieve better metabolic control because it is designed to be absorbed more like a natural protein (Nadia Giarratana, 2018).

PKU GOLIKE (bars or granules) is NOT a “normal food product”. Medical formulas are the primary source of nutrition for this patient and can help to avoid devastating consequences of PKU if they are provided PKU GOLIKE (bars or granules).

Sincerely,

(physicians signature)

Physicians phone

# References

Anita MacDonald\*, C. A. (2020). An Observational Study Evaluating the Introduction of a Prolonged-Release Protein Substitute to the Dietary management of Children with Phenylketonuria. *NUTRIENTS*, 2686.

Nadia Giarratana, P. (2018). A New Phe-Free Protein Synthesis Engineered to Allow a Physiological Absorption of Free Amino Acids for Phenylketonuria. *THE JOURNAL OF INBORN ERRORS OF METABOLISM & SCREENING*, Volume 6: 1-9.