**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

**Subject**: Request for Coverage/Reimbursement of PKU GOLIKE Plus (Eton Pharmaceuticals, Inc.)

To Whom It May Concern:

I am writing this letter of medical necessity regarding the treatment of (Patient’s Name), This patient was born with a genetic disorder, Phenylketonuria (PKU), which is an inborn error of metabolism. Based on their condition and clinical history, I am requesting that the medical formula PKU GOLIKE Plus be covered by (Insurance Company) for (Patient’s Name).

PKU is an incurable, lifelong disease in which the amino acid phenylalanine (Phe) cannot be metabolized by the body. This leads to increased levels of 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 non-Phe medical formula that provides the necessary amino acids for proper growth and development.

To date, my patient has failed to tolerate and/or thrive on other PKU formulas including: (insert failed formulas here) as evidenced by their failure to meet (include any parameters deemed necessary, examples might include: weight gain goals, GI discomfort, emesis, diarrhea, constipation, heartburn/GERD, bloating, excessive gas, stomach aches/pains, increased mucus production, etc.).

PKU GOLIKE Plus has a unique Physiomimic Technology™ that releases amino acids slowly, much like natural proteins. Its special coating also conceals 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 liquid1. Patients on PKU GOLIKE may help achieve better metabolic control because it is designed to be absorbed more like a natural protein2.

PKU GOLIKE Plus is NOT a “normal food product”. Medical formulas are the primary source of nutrition for this patient, and if they are provided PKU GOLIKE Plus, they can help them avoid the devastating consequences of PKU.

PKU GOLIKE Plus is ideally suited for my patient, and I am prescribing \_\_\_\_ grams/protein per day. Your approval of this request for assistance with medical care and reimbursement of the formula would have a significant positive impact on this patient’s health.

Sincerely,

(Physicians Signature)

(Physician’s Name/Title/Credentials)

(Physicians Phone)

**References**

1. MacDonald, A et al. An observational study evaluating the introduction of a prolonged-release protein substitute to the dietary management of children with phenylketonuria. *Nutrients* 2020;12:2686.
2. Giarratana, P et al. A new phe-free protein substitute engineered to allow a physiological absorption of free amino acids for phenylketonuria. *Journal of Inborn Errors of Metabolism & Screening.* 2018;6:1-9.