**Date**:

**To**: *Insurance Co.*

*Insurance Co. Address*

**From**: *Physician name*

**SUBJECT:** Request for coverage/reimbursement for Functional Formularies Keto Peptide feeding tube formula.

I am requesting insurance coverage and reimbursement on behalf of my patient, *name*, *DOB dd/mm/yyyy*, who has been under my care since \_\_\_/\_\_\_\_/\_\_\_. I have prescribed Functional Formularies Keto Peptide feeding tube formula for the dietary management of [*insert* *diagnosis or condition].* His/her seizures are occurring *X* times each day, despite attempts at seizure control with *[name of anti-convulsant(s) and other epilepsy treatments].*

About 1 in 3 people with epilepsy have an intractable form, meaning that their seizures cannot be controlled with antiepileptic medications. Additionally, some individuals do not tolerate these medications. For these patients, alternative options include the ketogenic diet, brain surgery, or vagus nerve stimulation (VNS). For my patient, I have prescribed the ketogenic diet that *[patient’s name]* takes enterally through a gastrointestinal tube. Prior to starting the ketogenic diet, *[patient’s name]* was utilizing *[formula name].*

I am prescribing Keto Peptide as a part of this patient's treatment plan for the health benefits that it may provide considering their medical diagnosis and individual nutritional needs. The patient requires this formula for their nutritional management as a result of his/her diagnosis and/or condition, and not as a convenience.

*[IMPORTANT: Verify medical necessity for formula, including diagnosis, documented failure or intolerance to other formulas, current height/weight, growth chart data, history of weight loss, pertinent lab results, medications, and potential outcome if the formula is denied.]*

The ketogenic diet is a high fat, low carbohydrate, and moderate, but adequate protein-containing diet. The diet is individually calculated and prescribed to produce a sufficient level of nutritional ketosis required to suppress the patient’s seizures. The efficacy of the ketogenic diet for the management of intractable epilepsy is well documented (see clinical references in Appendix A). *[Patient name]*’s custom ketogenic formula is prepared with Functional Formularies Keto Peptide *[and water, additives, etc.]*. Functional Formularies Keto Peptide is a ketogenic enteral peptide formula formulated for all patients for the clinical dietary management of intractable epilepsy, glucose transporter type 1 deficiency syndrome (Glut-1 DS), pyruvate dehydrogenase deficiency (PDH), and other disorders that benefit from a ketogenic diet.

Keto Peptide is a commercially prepared blenderized ketogenic formula designed to be well tolerated by patients with significant gastrointestinal impairment, such as *[Patient name]*. He/she receives their formula via feeding tube exclusively.

My patient was *[X]*kg in weight at his last face to face encounter on *dd/mm/yyyy*. In order to meet *[patient’s name]* nutritional needs, he/she will require approximately *[xxxx]* calories per day from Keto Peptide by Functional Formularies in order to have enough to mix his/her current custom formula recipe that has been designed by my ketogenic dietitian at *[insert facility name]*.

Keto Peptide is designed for all patients that may benefit from an organic, plant-based, ketogenic, peptide formula made with real whole food ingredients that are free of milk, eggs, wheat, soy, sesame, fish, shellfish, and peanuts. Keto Peptide meets all food safety requirements as well as all GRAS, HACCP, and CGMP standards. It is produced in a FDA/USDA registered facility with a USDA inspector on-site. It is shelf-stable, requires no refrigeration, and has a two-year shelf life.

Keto Peptide is intended for use under medical supervision. Functional Formularies Keto Peptide feeding tube formula is recognized by the Centers for Medicare and Medicaid Services (CMS) as “an enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), including fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube”, found in HCPCS Category B4153 (adults) and B4161 (pediatric).

We are requesting that, because these components comprise an antiepileptic therapy rather than just a nutritional formula, they be covered under your policies.

Thank you for reviewing this request. Please contact me should you require any additional information.

Sincerely,

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*Signature of prescribing MD, PA-C, ARNP Date*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Printed Name of prescribing MD, PA-C, ARNP*

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*Title           Phone/Email*

**Attachments:** You may want to include pertinent information supporting your directive including Clinical Notes, Reports, Prescriptions, and/or other relevant documentation.

**Appendix A: Selected References Demonstrated the Efficacy of the Ketogenic Diet for Intractable Epilepsy**

1. Kossoff EH., et al. Optimal clinical management of children receiving dietary therapies for epilepsy: Updated recommendations of the International Ketogenic Diet Study Group. *Epilepsia Open*. 2018;3(2):175-192.
2. Cervenka M., et al. International Recommendations for the Management of Adults Treated with Ketogenic Diet Therapies. *Neurol Clin Pract*. 2021;11(5):385-397.
3. Roehl K., Sewak S. Practice Paper of the Academy of Nutrition and Dietetics: Classic and Modified Ketogenic Diets for Treatment of Epilepsy. *J Acad Nutr Diet*. 2017 Aug;117(8):1279-1292.
4. Dressler A., et al. Long-term outcome and tolerability of the ketogenic diet in drug-resistant childhood epilepsy--the Austrian experience. *Seizure*. 2010 Sep;19(7):404-8.
5. Patel A., et al. Long-term outcomes of children treated with the ketogenic diet in the past. *Epilepsia*. 2010 Jul;51(7):1277-82.
6. Kossoff EH. The ketogenic diet: an appropriate first-line therapy? *Expert Rev Neurother*. 2010 Jun;10(6):843-5.
7. Coppola G., et al. Ketogenic diet for the treatment of catastrophic epileptic encephalopathies in childhood. *Eur J Paediatr Neurol*. 2010 May;14(3):229-34.
8. Kossoff EH., et al. Ketogenic Diets: An Update for Child Neurologists. *J Child Neurol.* 2009 Aug;24(8):979-88.
9. Bough KJ., et al. Anticonvulsant mechanisms of the ketogenic diet. *Epilepsia*. 2007 Jan;48(1):43- 58.
10. Groesbeck DK., et al. Long-term use of the ketogenic diet in the treatment of epilepsy. *Dev Med Child Neurol*. 2006 Dec;48(12):978-81.
11. Henderson CB., et al. Efficacy of the ketogenic diet as a treatment option for epilepsy: meta-analysis. *J Child Neurol*. 2006 Mar;21(3):193-8.
12. Rubenstein JE., et al. Experience in the use of the ketogenic diet as early therapy. *J Child Neurol*. 2005 Jan;20(1):31-4.
13. Hemingway C., et al. The ketogenic diet: a 3- to 6-year follow-up of 150 children enrolled prospectively. *Pediatrics*. 2001 Oct;108(4):898-905.
14. Lefevre F., Aronson N. Ketogenic Diet for the Treatment of Refractory Epilepsy in Children: A Systematic Review of Efficacy. *Pediatrics*. 2000 Apr;105(4):898-905.

**Appendix B: References for Decreased Medical Costs Associated with the Ketogenic Diet for Intractable Epilepsy**

1. Whiting S., et al. Decreased health care utilization and health care costs in the inpatient and emergency department setting following initiation of ketogenic diet in pediatric patients: the experience in Ontario, Canada**.** *Epilepsy Res*. 2017;131:51-57.
2. Mandel A., et al. Medical costs are reduced when children with intractable epilepsy are successfully treated with the ketogenic diet. *J Am Diet Assoc.* 2002;102(3):396-398.
3. Gilbert DL., et al. Medication cost reduction in children on the ketogenic diet: data from a prospective study. *J Child Neurol.* 1999;14(7):469-471.
4. Kayyali H., et al. Ketogenic Diet Decreases Emergency Room Visits and Hospitalizations Related to Epilepsy. *Epilepsy Res Treat*. 2016;2016:5873208.