**LETTER OF MEDICAL NECESSITY: INTRACTABLE SEIZURE DISORDER**

**Date:**

**Patient:**

**D.O.B:**

**Policy Number:**

Attention Case Manager:

This letter of medical necessity is regarding the nutrition management of **[PATIENT NAME]**. This patientis a **[AGE] [GENDER]** with a diagnosis of **[DIAGNOSIS]** and an **intractable seizure disorder** **(ICD 10: [INSERT #])**. His/Her seizures are occurring **[#]** times each day, despite attempts at seizure control with **[NAME OF ANTICONVULSANTS AND OTHER EPILEPSY TREATMENTS]**.

Approximately 1/3 of epilepsy patients have an intractable form, meaning that their seizures cannot be controlled with antiepileptic medications. For these patients, alternative options include the Ketogenic diet, brain surgery, or vagus nerve stimulation (VNS). For this patient, the ketogenic diet has been prescribed.

The ketogenic diet is a high fat, adequate protein, low carbohydrate dietary treatment that is individually calculated and prescribed to produce adequate ketosis to suppress a patient’s seizures. The efficacy of the ketogenic diet for the management of intractable epilepsy is well documented (see clinical references in Appendix A).

Ketogenic therapy severely restricts the intake of dairy products, fruit, vegetables, cereals and grains. As such, the potential for nutrient deficiency is a significant risk. KetoVie 4:1 is a medical food specifically designed to provide the necessary nutrients to support ketogenic diet therapy. Nutrient deficiencies such as carnitine, selenium, calcium, vitamin D and protein, are common with ketogenic therapies. In order to help prevent these deficiencies, KetoVie provides 50mg carnitine, 22mcg selenium, 260mg calcium, 250IU vitamin D and 8.5g protein per 250mL serving, with a 4:1 (fat to carbohydrate and protein) ketogenic ratio. KetoVie 4:1 additionally contains medium chain triglycerides (MCTs) which aid in reaching the desired level of ketosis for maximum benefit. KetoVie can be offered orally to support optimal levels of ketosis or as a sole source tube feeding.

The term medical food/formula, is defined in section 5(b) of the Orphan Drug Act {21 U.S.C. 360ee (b) (3)}: a “food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”

In order to meet **[PATIENT NAME]** nutritional needs, he/she will require **[# OF CALORIES**] calories per day from KetoVie 4:1 medical food (see monthly volume prescription chart below for corresponding amount of product). KetoVie 4:1 is only available by prescription through a pharmacy, durable medical equipment (DME) company or directly from the manufacturer Cambrooke Therapeutics, Inc.

We are requesting that, because these components support an antiepileptic therapy, they be covered under your policies. If seizure control can be reached with a ketogenic diet, more invasive and costly procedures such as brain surgery or VNS may be avoided and seizure medications may be reduced or even discontinued (see clinical references in Appendix B).

We appreciate your attention to this request for **[PATIENT NAME]** medical food/formula, **KetoVie 4:1**, to be covered by their current medical insurance. Please do not hesitate to contact us if you have any questions.

Sincerely,

**[Physician name, M.D. other credentials, contact info, clinic name]**

**[Dietitian name, RD, LDN other credentials Center/Hospital/Institution/Practice]**

Cc: **[Parents’ names] and Medical Records**

Attachments: Prescription, Medical Records, Growth Records,and Clinical References for the Ketogenic Diet

**Monthly Volume Prescription:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Calories/day** | **Calories/month** | **Tetras of KetoVie/month** | **Cases/month** |
| **Vanilla** | | | |
| 360 or less | 10,800 | 30 | 1 |
| 361 - 720 | 21,600 | 60 | 2 |
| 721 – 1,080 | 32,400 | 90 | 3 |
| 1,081 – 1,440 | 43,200 | 120 | 4 |
| 1,441 – 1,800 | 54,000 | 150 | 5 |
| **Chocolate** | | | |
| 390 or less | 11,700 | 30 | 1 |
| 391 - 780 | 23,400 | 60 | 2 |
| 781 - 1,170 | 35,100 | 90 | 3 |
| 1,171 - 1,560 | 46,800 | 120 | 4 |
| 1,561 - 1,950 | 58,500 | 150 | 5 |

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

1. Dressler A, et al. (2010). Long-term outcome and tolerability of the ketogenic diet in drug-resistant childhood epilepsy--the Austrian experience. Seizure. Sep;19(7):404-8.
2. Patel A, et al. (2010). Long-term outcomes of children treated with the ketogenic diet in the past. Epilepsia. Jul;51(7):1277-82.
3. Kossoff EH. (2010). The ketogenic diet: an appropriate first-line therapy? Expert Rev Neurother. Jun;10(6):843-5.
4. Coppola G, et al. (2010). Ketogenic diet for the treatment of catastrophic epileptic encephalopathies in childhood. Eur J Paediatr Neurol. May;14(3):229-34.
5. Kossoff EH, et al. (2009). Ketogenic Diets: An Update for Child Neurologists. J Child Neurol. Aug;24(8):979-88.
6. Bough KJ, et al. (2007). Anticonvulsant mechanisms of the ketogenic diet. Epilepsia. Jan;48(1):43-58.
7. Groesbeck DK, et al. (2006). Long-term use of the ketogenic diet in the treatment of epilepsy. Dev Med Child Neurol. Dec;48(12):978-81.
8. Henderson CB, et al. (2006). Efficacy of the ketogenic diet as a treatment option for epilepsy: meta-analysis. J Child Neurol. Mar;21(3):193-8.
9. Rubenstein JE, et al. (2005). Experience in the use of the ketogenic diet as early therapy. J Child Neurol. Jan;20(1):31-4.
10. Kossoff EH, et al. (2004). Benefits of an all-liquid ketogenic diet. Epilepsia. Sep;45(9):1163.
11. Hemingway C, et al. (2001). The ketogenic diet: a 3- to 6-year follow-up of 150 children enrolled prospectively. Pediatrics. 2001 Oct;108(4):898-905.
12. Freeman JM, et al. (1998). The efficacy of the ketogenic diet-1998: a prospective evaluation of intervention in 150 children. Pediatrics. Dec;102(6):1358-63.

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

1. Whiting, S., Donner, E., RamachandreanNair, R., Grabowski, J., Jetté, N., & Rodriguez Duque, R. (2017). 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. J. Eplepsyres March: 131,51-57.
2. Swink TD, Timmler TL, Weatherford KJ, Ruggles KH. (2003). Decreased cost of care associated with the ketogenic diet for treatment of medically refractory epilepsy [abstract 2.316]. Epilepsia.;44(suppl 9);283.
3. Mandel A, Ballew M, Pina-Garza JE, Stalmasek V, Clemens LH. (2002). Medical costs are reduced when children with intractable epilepsy are successfully treated with the ketogenic diet. J Am Diet Assoc. Mar;102(3):396-8.
4. Gilbert DL, Pyzik PL, Vining EP, Freeman JM. (1999). Medication cost reduction in children on the ketogenic diet: data from a prospective study. J Child Neurol. Jul;14(7):469-71.