**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]**. They require liquid enteral formula because [**REASON FOR ENTERAL FORMULA**].

Approximately one-third 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). The ketogenic diet has been prescribed as the best option for treatment of intractable epilepsy for this patient.

The ketogenic diet is a high fat, adequate protein, low carbohydrate dietary treatment individually calculated and medically monitored 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 carbohydrates such as dairy products, fruit, vegetables, cereals, and grains. Limited intake of food groups increases the potential for nutrient deficiency and is a significant risk for malnutrition. KetoVie 4:1 is a nutritionally complete medical food which provides the necessary nutrients to optimize ketogenic diet therapy. Nutrient deficiencies such as carnitine, selenium, calcium, vitamin D and protein, are common with ketogenic therapies. To help prevent these deficiencies, KetoVie provides 50 mg carnitine, 23 mcg selenium, 283-330 mg calcium\*, 6 mcg vitamin D and 8.2-8.6g protein\* per 250 mL serving, with a 4:1 (fat to carbohydrate and protein) ketogenic ratio. KetoVie 4:1 additionally contains medium chain triglycerides (MCTs) which aids with GI absorption as well as promoting the desired level of ketosis for maximum benefit. KetoVie 4:1 can be offered orally to support optimal levels of ketosis or as a sole source tube feeding. (*\*Range depends on flavor variety.)*

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.”

To meet **[PATIENT NAME]** prescribed ketogenic therapy, he/she will require **[# OF CALORIES, #g CARBOHYDRATES, #g PROTEIN]** within the defined ketogenic diet ratio and supplemented with micronutrients. It is not possible to meet this need with standard enteral formulas. KetoVie 4:1 medical food provides the balance of nutrients for this prescribed ketogenic therapy (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, Ajinomoto Cambrooke, Inc.

Because these components support antiepileptic therapy and will address the risk of malnutrition, we are requesting KetoVie 4:1 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 his/her 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:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product** | **Calories per day** | **Calories per month** | **Tetras of KetoVie 4:1 per month** | **Cases per month** |
| KetoVie 4:1  Vanilla | 370 or less | 11,100 | 30 | 1 |
| 371 – 740 | 22,200 | 60 | 2 |
| 741 – 1,110 | 33,300 | 90 | 3 |
| 1,111 – 1,480 | 44,400 | 120 | 4 |
| 1,481 – 1,850 | 55,500 | 150 | 5 |
| KetoVie 4:1 Chocolate | 400 or less | 12,00 | 30 | 1 |
| 401 - 800 | 24,000 | 60 | 2 |
| 801 - 1,200 | 36,000 | 90 | 3 |
| 1,201 - 1,600 | 48,000 | 120 | 4 |
| 1,601 – 2,000 | 60,000 | 150 | 5 |
| KetoVie 4:1 Unflavored | 375 or less | 11,250 | 30 | 1 |
| 376 - 750 | 22,500 | 60 | 2 |
| 751 – 1,125 | 33,750 | 90 | 3 |
| 1,126 – 1,500 | 45,000 | 120 | 4 |
| 1,501 – 1,875 | 56,250 | 150 | 5 |
| KetoVie 4:1 Plant-based Protein Vanilla | 375 or less | 11,250 | 30 | 1 |
| 376 - 750 | 22,500 | 60 | 2 |
| 751 – 1,125 | 33,750 | 90 | 3 |
| 1,126 – 1,500 | 45,000 | 120 | 4 |
| 1,501 – 1,875 | 56,250 | 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.