KETOGENIC DIET AS A TREATMENT FOR EPILEPSY
MED201.012
POSTED DATE: 8/22/2003
EFFECTIVE DATE: 12/1/2003

COVERAGE:

During an inpatient hospitalization ONLY, management of a ketogenic diet is considered medically necessary in children with refractory epilepsy (inadequate control of seizures, e.g., multiple seizures per day, despite optimal treatment with conventional medications, e.g., prior use of up to 6-7 individual antiepileptic drugs [AEDs]).

SPECIAL POLICY COMMENT:
Outpatient ketogenic diet management is not addressed in this policy.

FOR YOUR INFORMATION - Outpatient ketogenic diet management, nutrition counseling, food, and diet items/aids, may have coverage limitations or exclusions by the contract, specifically or as over the counter items.

DESCRIPTION:

The Ketogenic Diet is a high-fat, low-protein, low-carbohydrate diet developed to treat children with difficult to control or inadequate control of epileptic seizures (tonic, atonic and tonic-clonic) which cause children to fall to the ground and injure themselves, despite treatment with conventional medications. These children are diagnosed with drug-refractory or intractable epilepsy. They have severe seizure disorders, with a high mean seizure frequency of up to 7 to 13 seizures per day. They have an extensive history of antiepileptic drug (AEDs) usage of up to 6 to 7 different AEDs.

The composition of the diet induces ketosis, a physiologic state in which circulating ketone bodies are used as the primary fuel source in the absence of simple sugars. During the ketogenic process, the body uses more fat for energy than normal. Ketosis may inhibit seizures through an unknown mechanism. The literature suggests the mechanism of action of the ketogenic diet appears to rely on a fundamental change in the brain's metabolism from that of a glucose-based energy action to a ketone-based action. The side effects appear fewer than with most medications. The ketogenic diet has gained attention as a treatment option in children with epilepsy that is resistant (refractory) to medications or as an alternative approach to trying multiple medications or surgical intervention.

The ketogenic diet is quite restrictive, requiring the cooperation of the patient, family, and an appropriately trained dietitian. The ratio of fat to carbohydrates must be strictly maintained (the precise contents of each food item must be known and exactly measured) and fluid consumption must be limited. The diet is so strict that even medications and vitamins must be sugar-free.
Long-term effects of this diet are unknown. The diet is intended for 2-3 years, but is not known if many patients will continue past that time period. Given the restrictions, compliance with the diet can be problematic. Noncompliance with the diet can be high, on average 45% discontinue the diet at 12 months. Generally, noncompliance correlates with the efficacy of the diet reducing seizures. Children who are over 10 years of age have well-established dietary habits and preferences. They may have the greatest non-compliance rate, perhaps due to reduced palatability of meals and inconvenience.

As currently practiced, the ketogenic diet management is initiated in the hospital setting. Children are admitted to the hospital and fasted for 1 to 2 days. The diet is then begun gradually over a number of days. A full ketogenic diet is attained by approximately day 5 in most children, at which time the patient is discharged and followed as an outpatient. The main reason for hospitalization is the period of fasting. Fasting potentially exposes children to dehydration and metabolic derangement that could become life threatening if not properly monitored and treated. During the hospitalization, the family is provided with an intense educational program required to maintain the ketogenic diet once discharged. The educational program and nutrition counseling may last 20 hours during the hospital stay. An average hospitalization is 5 days. Most families can successfully manage the diet within 3 to 4 weeks following the hospitalization and educational program.

This policy does not address outpatient management of ketogenic diets, ONLY inpatient ketogenic diet initiation.

RATIONALE:

This policy is based on a 1998 TEC assessment that offered the following conclusions:

- While the published data regarding ketogenic diets consists of uncontrolled case series, the data are consistent in showing that some children benefit from the ketogenic diet, as demonstrated by a significant reduction in seizure frequency; i.e., complete cessation of seizures in 16% of children, greater than 90% reduction in 32%, and a greater than 50% reduction in 56%.

- These results exceed any expected placebo effect or spontaneous remission of seizures.

As currently practiced, the ketogenic diet is typically initiated in an inpatient setting, principally to monitor the patient during the
initial fasting period, but also presumably to provide the intense education required to maintain a ketogenic diet once discharged. There are currently no data that focus on initiating the diet in the outpatient environment. However, the published studies do not explicitly delineate the adverse effects that occurred during the inpatient stay, and whether their management required hospitalization. Another possibility is the gradual initiation of the diet such that fasting (and hospitalization) would not be required. This approach should, in principle, achieve the same end point of ketosis, although over a longer time period. However, it is also possible that the fast itself is responsible for some degree of response seen in the published studies.

As part of the TEC assessment, 14 programs offering ketogenic diets were surveyed. Thirteen of the 14 programs reported that they always or virtually always instituted the diet in the inpatient setting. Four programs reported that they would rarely institute the diet in the outpatient setting under special circumstances, such as when it was being restarted after a period off the diet. One program reported that they routinely initiate the diet in the outpatient setting and that they feel that their results were comparable to other centers that followed the inpatient protocol. This program reported that they have not published any data on their outcomes nor formally presented outcome data in any scientific forums. While these data do not represent a comprehensive catalogue of practice patterns, it is clear that the most common approach is initiation of the diet in the inpatient setting, but that there are instances, in which the diet has been successfully initiated in the outpatient setting.

PRICING:

None

REFERENCES:

• "Ketogenic Diet as a Treatment of Refractory Epilepsy." BCBSA
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• "Epilepsy in Children: Other seizure treatment." 1999 Mayo Clinic
  (Web site/on-line 02/22/1999):
• "Epilepsy in Children: Treatment advances." 1999 Mayo Clinic (Web
  site/on-line 02/22/1999):
• TEC Assessment, 1998; Tab 20

DISCLAIMER:

State and federal law, as well as contract language, including
definitions and specific inclusions/exclusions, takes precedence over
Medical Policy and must be considered first in determining coverage.
The member’s contract benefits in effect on the date that services are
rendered must be used. Any benefits are subject to the payment of
premiums for the date on which services are rendered. Medical
technology is constantly evolving, and we reserve the right to review
and update Medical Policy periodically.
HMO Blue Texas physicians who are contracted/affiliated with a
capitated IPA/medical group must contact the IPA/medical group for
information regarding HMO claims/reimbursement information and other
general polices and procedures.