Molina Clinical Policy
Ketogenic Diet Induction for Treatment of Intractable Seizures in the Hospital Setting
Policy No. 344

Last Approval: 02/11/2026
Next Review Due By: February 2027

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Seizures are defined as paroxysmal disorders of the central nervous system characterized by abnormal cerebral neuronal discharge, with or without loss of consciousness. Seizures are broadly categorized as either focal or generalized based on whether the onset of abnormal electrical activity involves a focal region or both hemispheres of the brain. Seizures disorders have diverse etiologies, including genetic, idiopathic, and metabolic origins. Anti-epileptic medications are the first-line treatment; however, a substantial proportion of patients experience persistent seizures despite appropriate pharmacologic therapy.

Ketogenic diet therapy is a well-established non-pharmacologic treatment for drug resistant epilepsy, particularly in pediatric populations. The ketogenic diet is a high-fat diet, adequate-protein, and very low-carbohydrate dietary regimen that induces a state of ketosis. Reported adverse effects may include gastrointestinal symptoms, weight changes, nephrolithiasis, dyslipidemia, and mood or behavioral changes. While ketogenic diet therapy has demonstrated efficacy across a range of seizure types and epilepsy syndromes, successful treatment requires strict adherence and ongoing management by an interdisciplinary care team to monitor seizure control, nutritional status, growth and development, and metabolic parameters. Alternative dietary therapies with demonstrated benefit in reducing seizure frequency include the medium-chain triglyceride diet, modified Atkins diet, and low glycemic index treatment (Kossoff 2025).

Historically, initiation of the classic ketogenic diet in pediatric patients was commonly performed during a 3- to 5-day inpatient hospital admission. Although younger patients and those with medical comorbidities may be at higher risk for initiation-related complications, current evidence indicates that ketogenic diet therapy can often be safely initiated under observation or in outpatient settings when appropriate resources, education, and monitoring are available. Decisions regarding initiation setting, resource utilization, and the use of fasting should be individualized based on patient-specific clinical factors.

COVERAGE POLICY

1. Inpatient hospitalization solely for initiation of a ketogenic diet is considered **NOT medically necessary** in children and adolescents who are <18 years of age for the treatment of drug-resistant epilepsy, intractable seizures, and/or any other diagnosis. Initiation may be safely performed under an observational stay, outpatient setting, or home setting.

2. Inpatient hospitalization solely for initiation of a ketogenic diet is considered **experimental, investigational, and unproven** in adults who are >18 years of age for the treatment of drug-resistant epilepsy, intractable seizures and/or any other diagnosis due to insufficient peer reviewed medical literature.

DOCUMENTATION REQUIREMENTS: Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is

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not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Randomized Controlled Trials

Li et al. (2023) conducted a randomized controlled trial comparing the safety and efficacy of inpatient versus outpatient initiation of the ketogenic diet in pediatric patients with drug-resistant epilepsy. Eligible patients were ≤16 years of age, had failed at least two anti-epileptic medications, experienced a minimum of three countable seizures per week, and had caregivers capable of adhering to the ketogenic diet requirements. A total of 190 patients were randomized into outpatient (n=78) and inpatient (n=112) initiation groups. The inpatient group underwent hospital admission with close monitoring during the first week of diet initiation, whereas the outpatient group received a 1-day case admission for baseline assessment and caregiver education, followed by outpatient monitoring. All patients were followed for 12 months, with caregivers recording dietary adherence, seizure frequency, and adverse events. The primary clinical outcome was a ≥ 50% reduction in seizure frequency after initiation of the ketogenic diet assessed at 1, 3, 6, and 12 months. In the inpatient group, ≥50% seizure reduction was achieved in 25.41%, 43.09%, 49.35%, and 65.75% of patients at 1, 3, 6, and 12 months, respectively. Corresponding rates in the outpatient group were 31.94%, 51.39%, 56.25%, and 69.70%. Seizure reduction rates increased over time in both groups, with no clinically meaningful differences between initiation settings. There were no significant differences in height, weight, BMI, and BMI Z-score between the inpatient and outpatient groups over the 12-month period. Adverse events occurred in 43.05% of patients in the outpatient group and 42.20% of patients in the inpatient group, with no statistically significant difference (p=0.909). The most reported adverse events were gastrointestinal symptoms, anorexia, constipation, slowed growth, and sleep disturbances, with similar incidence across groups. The authors concluded that outpatient initiation of the ketogenic diet was safe and effective and resulted in comparable clinical outcomes to inpatient initiation.

Systematic Reviews and Meta-Analyses

Devi et al. (2023) conducted a systematic review and meta-analysis evaluating the short-term efficacy and safety of dietary therapies for childhood drug-resistant epilepsy. Randomized controlled trials assessing the ketogenic diet, medium-chain triglyceride diet, modified Atkins diet, and low glycemic index treatment were included. Study quality was assessed using the Cochrane risk-of-bias tool, and pooled effect sizes were calculated as odds ratios (ORs) with 95% confidence intervals (CIs) using a random-effects model. Primary outcomes included the proportion of patients achieving ≥50% and ≥90% seizure reduction within ≤3 months of treatment initiation. Twelve RCTs comprising 907 patients were analyzed. All dietary interventions demonstrated greater efficacy than care as usual for achieving ≥50% seizure reduction, including low glycemic index treatment (OR 24.7; 95% CI, 5.3–115.4), modified Atkins diet (OR 11.3; 95% CI, 5.1–25.1), and ketogenic diet (OR 8.6; 95% CI, 3.7–20.0). The ketogenic diet (OR 6.5; 95% CI, 2.3–18.0) and modified Atkins diet (OR 5.1; 95% CI, 2.2–12.0) were also superior to care as usual for achieving ≥90% seizure reduction. However, both the ketogenic diet (OR 8.6; 95% CI, 1.8–40.6) and modified Atkins diet (OR 6.5; 95% CI, 1.4–31.2) were associated with significantly higher discontinuation or noncompliance rates, largely attributable to adverse events and challenges with dietary adherence. The authors concluded that dietary therapies are effective for seizure reduction in children with drug-resistant epilepsy, with the modified Atkins diet having both a high probability of 50% or higher seizure reduction, demonstrating a favorable balance between efficacy and tolerability. The review highlighted the need for direct head-to-head comparative trials to further clarify relative effectiveness and adherence outcomes among dietary approaches.

Sourbron et al. (2022) performed a systematic review and meta-analysis of randomized controlled trials examining the effectiveness and tolerability of ketogenic diet therapies, including the classic ketogenic diet and the Modified Atkins Diet, in pediatric patients with refractory epilepsy. Five RCTs, reported across seven publications, were included, enrolling a total of 472 participants aged ≤18 years. Across included trials, a reduction in seizure frequency of at least 50% was observed in 35% to 56% of patients receiving dietary therapy, compared with 6% to 18% of patients in control groups. Pooled analysis demonstrated a statistically significant improvement in seizure outcomes with ketogenic diet therapy relative to control treatment (p<0.001). Data on secondary outcomes, such as seizure severity and quality of life, were limited and inconsistently reported, preventing firm conclusions. Gastrointestinal symptoms were the most

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frequently reported adverse effects, and serious adverse events were not identified. The authors concluded that ketogenic diet therapies represent a reasonable treatment option for children and adolescents with drug-resistant epilepsy who are not candidates for epilepsy surgery, while emphasizing the need for future multicenter, long-term studies to better characterize biomarkers, sustained efficacy, and safety.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Ruiz-Herrero et al. (2021) conducted a retrospective, descriptive, and observational study on the use of ketogenic diets in children under the age of two. Forty-two children treated between 2000-2018 were analyzed; 40 children started a classic ketogenic diet with four patients transferred to a Modified Atkins Diet. At follow-up, 79% of infants remained on a ketogenic diet at 3 months; at six months 57% remained on the diet, 38% at 12 months and 17% at 24 months. A reduction in seizures of ≥50% (when compared to baseline) was found in 50%, 45%, 38% and 17% at 3, 6, 12 and 24 months, respectively. Seizure control was excellent with a reduction of >90% in 33% (at 3 months), 31% (at 6 months), 26% (at 12 months) and 12% (at 24 months). The mean length of a ketogenic diet was 390 days (16 days to 4.9 years). Early adverse effects occurred in 40% of infants during month one; the most common were asymptomatic hypoglycemia and gastrointestinal issues. Hypercalciuria and dyslipidemia were reported as late-onset side effects. The classic ketogenic diet is the most accepted diet in infants.

Mir et al. (2020) conducted a retrospective chart review on the incidence of potentially serious adverse events during hospital-based ketogenic diet initiation among children with drug-resistant epilepsy. A total of 66 children were analyzed over the course of their inpatient hospital stay for the initiation of the classic ketogenic diet. The mean age at the initiation of the ketogenic diet was 48.0 ± 38.4 months, mean weight was 14.6 ± 6.3 kg, and median number of anticonvulsant medications used at the time of diet initiation was three. Adverse events occurred in 28.7% of patients, specifically hypoglycemia (20%), hypoactivity (6.1%), somnolence (3%), and vomiting (7.6%). The groups' urine ketone levels on all 5 days were compared, and a statistically significant difference was found on day 3 (P = 0.026). A statistically significant difference in the serum bicarbonate levels (P = 0.038) was found between the patients taking topiramate and those not taking it. The authors concluded that adverse event rates during initiation were low and easily managed with basic medical intervention; however, children less than 3 years old and underweight at the time of initiation were found to have higher risk for adverse events. Hypoglycemia was the most common adverse event, and patients taking topiramate needed closer monitoring of serum bicarbonate levels than their counterparts. In conclusion, carefully selected patients may initiate the ketogenic diet in the outpatient setting with close monitoring if parents are prepared with education and resources to treat adverse events.

Van der Louw et al. (2019) conducted a retrospective observational non-inferiority study evaluating the induction of a ketogenic diet in children with intractable epilepsy in the outpatient setting. Due to inpatient hospitalizations being a costly intervention, the study aimed at comparing the safety, efficacy, and cost effectiveness outpatient versus inpatient ketogenic diet induction. The team reviewed the charts of 105 patients who underwent ketogenic diet induction between 2001-2017 and were under the age of 18 years old. The main outcomes were evaluating effectiveness defined as at least a 50% reduction in seizures, safety defined as measuring the number of emergency department visits and complications, and economic impact defined as total cost of treatment. Of those that underwent diet initiation inpatient, 43 patients, at three months the ketogenic diet was effective in 63% of patients versus 61% in the 62 patients who underwent diet initiation outpatient. Safety metrics revealed ketogenic diet induction was considered safe in 36% of the outpatient group versus 29% in the inpatient group. Both the effectiveness and safety outcomes revealed the non-inferiority of inducing a ketogenic diet in the outpatient setting. Lastly, calculated in euros, the cost of outpatient induction was € 2901 per patient, versus € 8195 per patient in the inpatient setting; thus, leading to the conclusion that outpatient induction of the ketogenic diet in patients with intractable epilepsy is safe, effective, and cost effective.

National and Specialty Organizations

The **International Ketogenic Diet Study Group (IKDSG)** published updated guidelines in 2018 *Optimal clinical management of children receiving dietary therapies for epilepsy* which reevaluated best practices originally published in 2008. The IKDSG recommends ketogenic diets for children after two antiseizure drugs have failed. The guidelines state initiation is often started during inpatient admission but can also safely be initiated in the outpatient setting depending on a variety of factors such as familial compliance and resources. The guidelines emphasize flexibility in the initiation process based on family situation/ needs, patient's age, and whether fasting is necessary. In addition, the IKDSG guidelines include information on the management of children on a ketogenic diet with respect to frequency of

follow up visits, nutrition, laboratory results, side effects, and discontinuation when appropriate. Updates made in 2018 focus on the decrease in use of fasting at initiation of a ketogenic diet, evidence to support alternative diets Modified Atkins Diet and Low Glycemic Index Treatment, utilizing a non-fasting classic ketogenic diet for children under age 2, implementing a one-month follow-up visit, and further explanations of ideal scenarios to implement a ketogenic diet. (Kossoff et al. 2018).

The **National Institute for Clinical Excellence (NICE)** (2025) published a clinical guideline titled *Epilepsies in Children, Young People, and Adults,* which address the diagnosis and management of epilepsy across primary, secondary, and tertiary care settings. The guideline includes recommendations on ketogenic diet therapies, stating that a ketogenic diet may be considered under the guidance of a tertiary epilepsy specialist for individuals with certain childhood-onset epilepsy syndromes (e.g., GLUT1 deficiency syndrome, pyruvate dehydrogenase deficiency–associated epilepsy, infantile spasms syndrome, Doose syndrome, Dravet syndrome, and Lennox–Gastaut syndrome) and for drug-resistant epilepsy when other treatment options have been unsuccessful or are not appropriate. NICE does not recommend ketogenic diets for routine use due to limited high-quality evidence, potential long-term health concerns, and resource considerations, and inpatient versus outpatient initiation management is not stipulated.

The *International Recommendations for the Management of Adults Treated with Ketogenic Diet Therapies* was published by Cervenka et al. (2021) and addressed selection of patients, contraindications and potential adverse events associated with ketogenic diet therapies, initiation guidelines, supplementation, monitoring, and discontinuation. The panel of experts recommends initiation of ketogenic diets via outpatient management; however, the authors did note that approximately 40% of ketogenic diets are initiated inpatient as treatment due to an admission for refractory or super refractory status epilepticus. Therefore, the sole initiation of a ketogenic diet does not require inpatient admission, as inpatient admission is most appropriate for the concurrent treatment of severe uncontrolled epilepsy.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
97802	Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes
97803	Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes
99499	Unlisted evaluation and management service [when specified as services related to ketogenic diet]

CODING DISCLAIMER: Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

02/11/2026	Policy reviewed. No changes to coverage criteria. Updated Summary of Medical Evidence and References.
02/12/2025	Policy reviewed. No changes to coverage criteria.
02/14/2024	Policy reviewed. No changes to coverage criteria, updated overview, and summary of medical evidence. IRO Peer Reviewed on January 9, 2024, by a practicing physician board certified in Neurology and Vascular Neurology.
02/08/2023	Policy reviewed, no changes to criteria.
02/09/2022	Policy reviewed; no changes to coverage criteria; updated Overview, Summary of Medical Evidence and Reference sections.
02/08/2021	Policy reviewed, no changes to criteria, references updated.
06/17/2020	Policy reviewed, no changes to criteria, references updated.
06/19/2019	New policy. IRO Peer reviewed March 29, 2019, by an Advanced Medical Reviews (AMR) practicing, board-certified physician in Neurology and Sleep Medicine.

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