Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

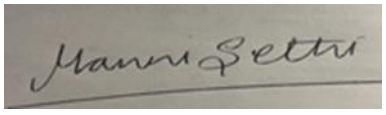
Plan: AmeriHealth Caritas Pennsylvania Community HealthChoices & Keystone First Community HealthChoices	Submission Date: 5/1/2026
Policy Number: CCP.1222	Effective Date: 7/1/2016 Revision Date: 4/1/2026
Policy Name: Ketone monitor for ketogenic diet in epilepsy	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Keystone First
Community HealthChoices

Ketone monitor for ketogenic diet in epilepsy

Clinical Policy ID: CCP.1222

Recent review date: 6

Next review date: 7

Policy contains: Ketone monitoring device; ketogenic diet in epilepsy.

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First Community HealthChoices, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

Ketone monitoring devices for members with epilepsy prescribed ketogenic diets are investigational/not clinically proven, and therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Urine test kits to test for ketones in members on the ketogenic diet for epilepsy.

Background

An estimated 3.4 million have active epilepsy, including 470,000 children (Centers for Disease Control and Prevention, 2020). In two-thirds of people with epilepsy, anti-seizure medications are effective at lessening or eliminating seizures. Surgery may be an option for focal seizures. Vagus nerve stimulation and ketogenic diets are options when medications are ineffective and surgery is not possible (Centers for Disease Control and Prevention, 2022).

The ketogenic diet is a special high-fat, low-carbohydrate diet developed in the 1920s to control epileptic seizures. While the underlying mechanism of action is not completely understood, the higher levels of ketones formed when the body uses fat for its primary energy source often lead to improved seizure control. The diet fell out of favor with the development of the seizure controlling medications. However, approximately 35% have medically intractable epilepsy, and there has been a resurgence of interest in the ketogenic diet as an effective treatment option (D'Andrea Meira, 2019).

The traditional ketogenic diet is administered under medical supervision. It entails an initial fasting and dehydration period, during which patients receive no food, and fluid intake is limited until ketones are present in the urine. Thereafter, a diet high in fat and low in carbohydrates and protein is introduced. Hospitalization may be necessary during an initial starvation period to induce marked ketosis and weight loss. The length of hospital stay depends on the proposed initial starvation period and generally should not exceed three days. More recently, low glycemic index treatment designed to simplify the implementation of the ketogenic diet, the modified Atkins diet, and the medium chain triglyceride diet have been introduced to improve adherence (D'Andrea Meira, 2019; Rezaei, 2018).

Strict compliance with this unpalatable dietary regimen is essential, along with careful monitoring of patient-reported seizure activity, growth (in children), health, and adverse effects. Ketone monitoring of serum or urine levels may be performed to assess ketosis and serve as a strategy to improve long-term dietary adherence. Urine testing, the most commonly-used technique, measures acetoacetate levels, while blood testing measures beta-hydroxybutyrate. Newer breath tests measure acetone (Keyto, 2020). In children with epilepsy on a ketone diet, monitoring is performed by physicians every one to three months, including growth (Kossoff, 2017).

There are several ketone monitoring devices on the market for patient use, which are mainly used for managing diabetes. Some examples are:

- FreeStyle® Optium Neo, which has a choice of tools designed to help people who use insulin.
- Precision Xtra® system and Precision Xtra blood ketone test strips.
- Ketonix® breath ketone monitor, which is a reusable breath ketone analyzer that measures the level of breath ketones. Measurements indicate the acetone in a user's breath, which is produced from the breakdown of acetoacetate in the person's blood.
- Nova Max® Plus glucose and ketone monitoring system.
- Walgreens TRUEresult® system.

Findings

Across guidelines, systematic reviews, and meta-analyses, the evidence consistently supports the ketogenic diet as an effective treatment for drug-resistant or medically refractory epilepsy in children, with more uncertain evidence in adults. Efficacy is most pronounced in the short term, adherence declines substantially over time, and adverse effects, primarily gastrointestinal, drive a proportion of discontinuations. The evidence on ketone monitoring reflects an evolution in guidance: earlier guidelines did not address it, while more recent professional guidance has positioned it as central to achieving and sustaining therapeutic ketosis and optimizing seizure outcomes. Emerging systematic evidence suggests that adherence, as objectively measured by ketone levels, correlates with improved seizure control, though the overall body of literature on ketone monitoring remains limited, and methodological constraints across studies call for cautious interpretation before revisions to clinical policy.

Guidelines

The major clinical guidelines agree that the ketogenic diet is appropriate for drug-resistant or refractory epilepsy when other treatment options have been exhausted, though they vary considerably in their attention to ketone monitoring. The National Institute for Health and Clinical Excellence recommended the ketogenic diet under the supervision of a tertiary epilepsy specialist for certain childhood-onset epilepsy syndromes and for drug-resistant epilepsy when other treatments are unsuccessful or inappropriate; this recommendation rested on expert consensus acknowledging benefit for small numbers of patients and the need for more research on effectiveness and long-term tolerability, with routine use not recommended (National Institute for Health and Care Excellence, 2022). Ketone monitoring was not addressed.

A practice paper of the Academy of Nutrition and Dietetics covered diet types, implementation, coordination of care, and the role of registered dietitian nutritionists without addressing ketone monitoring (Roehl, 2017). A guideline on the dietary management of inherited metabolic diseases specified laboratory and urine checks at baseline to screen for contraindications and deficiencies but provided no detail on the type, frequency, or role of ongoing ketone testing (van der Louw, 2016).

In contrast, the Italian League against Epilepsy Dietary Therapy Study Group placed ketone monitoring at the center of its guidance, characterizing it as essential to successful ketogenic dietary therapy for epilepsy. The guideline recommends regular blood beta-hydroxybutyrate measurement, with a target range of 2 to 5 mmol/L, to objectively verify therapeutic ketosis, support timely dietary adjustments, and establish individual therapeutic thresholds (De Giorgis, 2023). The guideline specifically prefers blood testing over urine testing based on superior accuracy and stronger correlation with seizure outcomes, and recommends intensifying monitoring during diet initiation, illness, or medication changes. When properly monitored, the ketogenic diet achieved greater than 50% seizure reduction in 35 to 56% of participants with drug-resistant epilepsy, with conditions such as glucose transporter type one deficiency potentially requiring higher ketone targets for optimal management (De Giorgis, 2023).

The first international best practice recommendations specifically for ketogenic dietitians, developed through the Ketogenic Dietitians Research Network and informed by both a systematic literature review and a survey of 111 dietitians across six continents, reflect similar conclusions regarding monitoring (Schoeler, 2025). Among respondents, 86% use blood ketone monitoring when initiating classical ketogenic diets, with 70% recommending beta-hydroxybutyrate testing twice daily; more than half (54%) advise reducing or discontinuing monitoring once levels stabilize. Most practitioners target blood beta-hydroxybutyrate levels of 2 to 6 mmol/L, and practitioners prefer blood monitoring over urine testing given its stronger correlation with seizure control.

For modified ketogenic diets, 57% of respondents recommend beginning ketone monitoring with the first meal, and 52% advise twice-daily testing during initiation. Additional clinical indications for checking ketones include symptoms of hyperketosis (89%), loss of seizure control (88%), and signs of illness (66%) (Schoeler, 2025).

Systematic Reviews

Systematic reviews collectively establish the ketogenic diet as an effective intervention for drug-resistant epilepsy across multiple age groups while documenting its adverse effects profile, adherence patterns, and, in more recent work, the relationship between ketone monitoring and treatment outcomes. A Cochrane review of 11 studies (n = 778) found supporting evidence for the ketogenic diet, though most included studies were small (Martin-McGill, 2018). An update by the same team covering 13 studies (n = 932) found evidence for effective use in treatment-refractory epilepsy in children, with uncertain results among adults (Martin-McGill, 2020). A broader systematic review of 24 articles concluded that various forms of the ketogenic diet appear tolerable and effective, with each of the 21 articles addressing epilepsy reporting seizure reduction compared to baseline (Christensen, 2021).

A systematic literature review found limited support for the diet specifically in refractory status epilepticus (Willems, 2020). A Cochrane review of seven randomized controlled trials of 427 children and adolescents found relatively similar results between ketogenic and modified Atkins diets, while cautioning that more research is needed to confirm those findings (Martin, 2016). A Cochrane review examining epilepsy combined with intellectual disabilities found only one study of poor quality, precluding meaningful conclusions (Jackson, 2015).

For infantile spasms, a systematic review of 13 studies (n = 341) found that a median of 64.7% of participants achieved greater than 50% spasm reduction in the short term, with 9.54% maintaining that threshold long term; participants with spasms of unknown etiology showed a better chance of achieving seizure freedom, with a risk ratio of 1.72 (Prezioso, 2018).

Adverse effects and non-adherence emerge as consistent themes across systematic reviews. A systematic review of 45 studies including seven randomized controlled trials found that the most common adverse events in children were gastrointestinal disturbances (40.6%), hyperlipidemia (12.8%), hyperuricemia (4.4%), lethargy (4.1%), infectious diseases (3.8%), and hypoproteinemia (3.8%), with severe events such as respiratory failure and pancreatitis occurring in under 0.5% of cases; nearly half of participants discontinued the diet, primarily due to lack of efficacy (Cai, 2017). A systematic review of 18 articles found that the dominant quality-of-life-related psychological burden for families of a child on the ketogenic diet was the need for counseling and clear outcomes expectations, with non-adherence and dropout rates reported as high and poorly documented (Poelzer, 2018).

Recent systematic evidence has shifted attention toward ketone monitoring as a mechanism through which adherence translates to improved seizure outcomes. A systematic review of 22 studies (n = 703) found that better dietary adherence, as measured by urinary or blood ketone levels, was associated with improved seizure control, though adherence declined from 79.7% at six months to 37.7% at 36 months (Lopes, 2024). An umbrella review covering 5,779 participants reported that the traditional ketogenic diet achieved greater than or equal to 50% seizure reduction in 60.6% of participants at three months versus 47.7% with modified diets, with both rates declining by 12 months (Chen, 2023).

In a review of 460 participants with pediatric epilepsy, gastrointestinal adverse effects occurring in 45 to 48% of cases contributed to non-adherence in 30 to 50%, while formula-based approaches incorporating ketone monitoring reached adherence rates of 81 to 100% (Faheem, 2024). A review of randomized controlled trials (n = 994) suggested that objective ketone monitoring may optimize treatment in medication-resistant cases, though the authors noted methodological limitations across the included studies (Parveen, 2024). Studies comparing outcomes with and without ketone monitoring, determining the correlation between ketone level and seizure reduction, identifying the optimal monitoring device, and establishing optimal timing remain needed.

Meta-Analyses

Among children and adolescents, a meta-analysis of 70 studies comparing the classical ketogenic diet with the modified Atkins diet revealed a non-significant trend toward higher efficacy for the modified Atkins group at months three and six (P > .05). The proportion of participants on the ketogenic diet achieving greater than or equal to 50% seizure reduction at months one, three, six, 12, and 24 were 62%, 60%, 52%, 42%, and 46%, respectively; for the modified Atkins group, reduction rates at months one, three, six, and 12 were 55%, 47%, 42%, and 29% (Rezaei, 2017).

In adults with drug-resistant epilepsy, a meta-analysis of 16 studies (n = 338) found a seizure freedom rate of 13%, a rate of greater than or equal to 50% seizure reduction of 53% overall, and a rate of greater than or equal to 50% reduction specifically in adults with intractable epilepsy of 27%; adverse reactions were mild but more common than with low glycemic index or low-dose fish oil diets (Liu, 2018).

In infants, a combined systematic review and meta-analysis of 33 studies (n = 534) found that 59% and 33% of participants achieved at least half and total seizure reduction, respectively, with retention at 84% at three months declining to 27% at 24 months (Lyons, 2020). A combined systematic review and meta-analysis of 18 studies in children with epilepsy showed similar efficacy at three and six months after treatment initiation, indicating that three-month results are reliable predictors of longer-term outcomes (Liu, 2019).

In 2026, we reorganized the findings section and added a new guideline from the Ketogenic Dietitians Research Network (Schoeler, 2025). No policy changes were warranted.

References

On March 12, 2026, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the

Centers for Medicare & Medicaid Services. Search terms were “ketogenic diet” and “ketone monitoring.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

2/2016: initial review date and clinical policy effective date: 7/2016

2/2017: Policy references updated.

2/2018: Policy references updated.

2/2019: Policy references updated. Policy number changed to CCP.1222.

2/2020:Policy references updated. .

4/2021: Policy references updated.

4/2022: Policy references updated.

4/2023: Policy references updated.

4/2024: Policy references updated.

4/2025: Policy references updated.

Related codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1222 This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code description
97802	Medical nutrition therapy, initial assessment and intervention, individual, face-to-face, each 15 minutes
97803	Medical nutrition therapy, reassessment and intervention, individual, face-to-face, each 15 minutes
97804	Medical nutrition therapy, group (2 or more individuals), each 30 minutes
G0270	Medical nutrition therapy, reassessment and subsequent intervention following a second referral in the same year for a change in diagnosis, medical condition, or treatment regimen, individual
G0271	Medical nutrition therapy, reassessment and subsequent intervention following a second referral in the same year for a change in diagnosis, medical condition, or treatment regimen, group (2 or more individuals), each 30 minutes