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: Keystone First	**Submission Date**: 1/2/2025
Policy Number: ccp.1275	**Effective Date:** 4/2017 **Revision Date:** December 1, 2024
Policy Name: Actigraphy	

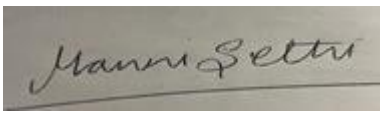
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☒ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Statewide PDL**

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

Please provide any clarifying information for the policy below:

See tracked changes below.

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

Keystone First
Family of Health Plans

Actigraphy

Clinical Policy ID: CCP.1275

Recent review date: 12/2024

Next review date: 4/2026

Policy contains: Actigraphy, circadian rhythm sleep disorders, polysomnography.

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's 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, 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's 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's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

Coverage policy

Actigraphy is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Facility based polysomnogram.
- Multiple sleep latency test.
- Split-night sleep studies.
- Unattended home polysomnograms.

Background

Actigraphy is a method of continually measuring patterns of human rest and activity cycles (unit movements) through an actimetry sensor. The technique was first used in the 1960s. The three main types of this device are sleep actigraphs, activity actigraphs, and movement actigraphs. Improvements in actigraphy technology include piezoelectric sensors, lithium batteries, and digital data storage (Martin, 2011).

Since the 1990s, the predominant purpose for the device has been to monitor sleep behavior. Sleep actigraphs, which are worn on the non-dominant arm like a wristwatch, often for a week or more, are used for disorders like insomnia, circadian rhythm sleep disorders, sleepiness, and restless leg syndrome. Unlike polysomnography, actigraphs permit movement by the patient while data are recorded. Information can be transmitted to a computer or can be analyzed in real time (Martin, 2011). Actigraphy offers a more convenient, less invasive, waterproof,

and lower cost option to polysomnography. Data from actigraphy can cover multiple nights, while polysomnography is performed in a laboratory, usually for only one or two nights (Fekedulegn, 2020).

Actigraphy is also used to measure activity behavior. Activity actigraphs are worn like a pedometer around the waist. They are used for several days and evaluate activities while awake, plus calories burned. Activity actigraphs are preferable for measuring and assessing activities during waking hours rather than sleep.

A third type of actigraphy is used to measure human movement to determine problems with gait and other physical impairments. Movement actigraphs are larger than sleep or activity actigraphs and are worn on the dominant shoulder. These actigraphs are three-dimensional (the others are one-dimensional) and are used only for several hours at a time (John, 2012).

Several devices have received 510(k) regulatory approval as Class II worn activity devices. The devices are intended to monitor the activity associated with movement during sleep and can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable (U.S. Food and Drug Administration, 2023).

Findings

The strongest evidence supporting the clinical efficacy of actigraphy lies in evaluation of sleep disorders. Polysomnography remains the standard of sleep measurement. Published studies of actigraphy compared the diagnostic characteristics relative to polysomnography or self-reported sleep logs as an adjunct to sleep logs or as a stand-alone procedure. Most studies were retrospective and heterogeneous with respect to device choices, time points, and threshold measurement, which made comparisons between studies difficult to quantify.

Efficacy will depend on the type of sleep disorder and sleep assessment procedure and the ability to impact diagnosis and treatment planning in prospective assessment. While actigraphy, including nonprescription devices, is increasingly incorporated into clinical practice to monitor treatment effectiveness and health of patients with sleep- and non-sleep-related disorders in a real-world setting, the supportive evidence is insufficient for these applications, as well.

The most recent American Academy of Sleep Medicine guideline issued recommendations for the use of actigraphy to evaluate sleep disorders and circadian rhythm sleep-wake disorders. The Academy limited the recommendations to clinical grade devices approved by the U.S. Food and Drug Administration as an actigraph or an equivalent device that uses an accelerometer to measure limb activity associated with movement during sleep for physiologic applications. The guideline excluded consumer wearable devices or nonprescription devices directly marketed to consumers (Smith, 2018a).

The Academy lists six recommendations for actigraphy graded as “conditional,” which reflect a low degree of certainty in the evidence regarding the outcome and appropriateness of the patient care strategy for all patients, and one strong recommendation, as follows (Smith, 2018a):

- To estimate sleep parameters in adult patients with insomnia disorder (conditional).
- To assess pediatric patients with insomnia disorder (conditional).
- To assess adults with circadian rhythm sleep-wake disorder (conditional).
- To assess pediatric patients with circadian rhythm sleep-wake disorder (conditional).
- To estimate total sleep time, integrated with home sleep apnea test devices during recording and in the absence of alternative objective measurements of total sleep time in adult patients with suspected sleep-disordered breathing (conditional).
- To monitor total sleep time prior to testing with the Multiple Sleep Latency Test in adult and pediatric patients with suspected central disorders of hypersomnolence (conditional).

- To estimate total sleep time in adult patients with suspected insufficient sleep syndrome (conditional).
- To not use actigraphy in place of electromyography for the diagnosis of periodic limb movement disorder in adult and pediatric patients (strong).

A meta-analysis of 81 studies served as the basis for the American Academy of Sleep Medicine's July 2018 guideline. Data demonstrate that, compared to sleep logs alone, actigraphy provides useful and often unique data for some sleep parameters in patients with suspected or diagnosed insomnia, circadian rhythm sleep-wake disorders, sleep-disordered breathing, central disorders of hypersomnolence, and adults with insufficient sleep syndrome, when conducted using validated algorithms with attention to sensitivity settings and standardized scoring procedures. In some cases, actigraphy estimates correlated more closely with polysomnography than sleep logs. Normative data and data on patient preferences for monitoring are needed. The data are not sufficient to recommend consumer products as a replacement for clinical devices that use validated sleep scoring algorithms, technologies, and procedures (Smith, 2018b).

A large review concludes that while actigraphy has a high sensitivity (ability to detect true wake and sleep), specificity is limited, as the device is unable to identify motionless wake. Specificity levels have been consistently low, at 26 to 77% in studies of healthy subjects, and 32% to 80% in various patients groups (de Zambotti, 2019).

A systematic review/meta-analysis of 96 studies (n = 4,134) included 762 adults who were healthy and 724 adults with chronic conditions. Compared to polysomnography, actigraphy overestimated total sleep time by an average of 22.42 minutes and underestimated sleep onset latency by 7.70 minutes. Differences were larger than in healthy adults (Conley, 2019).

A systematic review of 14 studies notes that actigraphy results can be heterogeneous, and thus, must be improved before replacing polysomnography (Plante, 2014).

A systematic review of 71 articles analyzed performance of home-based sleep measures; 75% of the articles compared actigraphy to polysomnography. In sleep onset among healthy populations, numerous studies showed no difference between the two techniques, although variations could be substantial. Results of actigraphy efficacy in insomnia – the most common sleep disorder – were mixed. Results in measuring sleep patterns of those with mental health disorders, i.e., biopolar disorder, major depression disorder, and schizophrenia, showed generally consistent results (Scott, 2020).

The following paragraphs present results of individual studies comparing polysomnography and actigraphy for diagnosing sleep disorders and assessing treatment effectiveness, with smaller numbers of subjects than systematic reviews/meta-analyses.

Actigraphy in children and adolescents

- Newborns (n = 40) admitted to a tertiary neonatal intensive care unit showed accurate sleep-wake detection by overnight actigraphy (on the ankle) compared with polysomnography (Unno, 2021).
- In children and adolescents referred for conditions such as snoring, enlarged tonsils, or restless sleep (n = 56), actigraphy underestimated total sleep time by 31.5 minutes, underestimated sleep efficiency by 12.9%, overestimated wake after sleep onset by 56.1 minutes, underestimated sleep onset by 10.2 minutes versus polysomnography (Burkart, 2021).
- Children (n = 26) with autism spectrum disorder showed similar results for actigraphy compared with polysomnography to evaluate sleep for most parameters (Yavuz-Kodat, 2019).
- Children (n = 17) and adolescents (n = 17) showed the Actiwatch 2 measured overnight sleep accurately compared to polysomnography, as did a new fitness tracker. Sensitivity for both the Actiwatch 2 and the fitness tracker was greater than .91 in both age groups. Specificity of the fitness tracker was greater than 0.77 in both age groups, while the specificity of the Actiwatch 2 was lower in children (0.68) and poor in adolescents (0.58). Both devices underestimated sleep time (Pesonen, 2018).

- Children ages 6-12 (n = 48) were randomized to groups with and without attention deficit hyperactivity disorder. Actigraphy provided good estimates for sleep duration for all groups and sleep-onset latency and sleep efficiency for the healthy group, but underestimated sleep duration, sleep efficiency, and sleep-onset latency for the attention deficit hyperactivity disorder group (Waldon, 2016).
- In children (n = 50) treated for craniopharyngioma, actigraphy produced similar results in sleep efficiency and sleep latency to polysomnography, but an average difference of 15 minutes in total sleep time and wake after sleep onset. The role of actigraphy for monitoring treatment response requires validation (Niel, 2019).

Actigraphy in adults

- Adults (n = 53) with insomnia showed greater detection with actigraphy for those with normal sleep duration (71.7% versus 41.5%) compared to polysomnography but less detection for those with short sleep duration (28.3% versus 58.5%) (Galbiati, 2021).
- In adults in a sleep laboratory setting (n = 281), actigraphy overestimated sleep time by a negligible amount (a larger amount in obstructive sleep apnea); underestimated sleep time in narcolepsy; and underestimated sleep efficiency, compared to polysomnography (Alakuijala, 2021).
- A diverse population of older adults (n = 46) using two new actigraphs in a home setting had a sensitivity of 97% and a specificity of 40% compared with polysomnography on sleep-wake classification (Regalia, 2021).
- Actigraphy and polysomnography results for total sleep time, sleep onset latency, sleep efficiency, and wakefulness after sleep onset were similar for participants with chronic insomnia disorder (n = 35), but not for those with sleep-disordered breathing (n = 31) (Choi, 2017).
- Among elderly males enrolled in the Osteoporotic Fractures in Men Study (n = 1,141), actigraphy (in combination with heart rate, heart rate variability, demographic, and psychological variables) did not accurately predict sleep quality compare with polysomnography (Faerman, 2020).
- Patients with traumatic brain injuries (n = 227) undergoing actigraphy showed underestimates of sleep disruption levels and poor agreement with sleep determined by polysomnography (Zeitzer, 2020).
- Pregnant women (n = 78) monitored overnight showed differences in sleep measures between actigraphy and polysomnography. The authors support actigraphy using the 10-by-10 scoring setting but not the default scoring setting (10-by-40) for this population (Zhu, 2018).

In 2018, the “International Biomarkers Workshop in Sleep and Circadian Science” held a workshop bringing together experts in sleep technologies, medical devices, sleep and circadian rhythm clinical research and practice in this specialty. The goals discussed were to distinguish the term “wearable,” and the define the metrics of the circadian rhythm measurement and sleep, assess current utilization of the technology, identify barriers, goals and opportunities for these devices to advance sleep and circadian science. Given the current state of technology and scientific advancement, wearable devices are still lacking validation against gold standard measurements. This remains the primary limitation for large scale use of wearable devices for sleep and circadian rhythm research (Depner, 2020).

In 2023, we added two systematic reviews to the policy, with no policy changes warranted. For measuring the prognostic value of actigraphy-quantified physical activity on mortality, morbidity, and health-related quality of life outcomes in patients with congestive heart failure, a systematic review of 15 cohort studies, one cross-sectional study, and one randomized controlled trial (n = 2,759) found actigraphy-quantified physical activity in a real-world setting is increasingly feasible for clinical practice but has variable prognostic value depending on the parameter considered (Tan, 2019).

For evaluating depressive or bipolar disorder symptoms, a systematic review of 38 studies (n = 3,758) found important measurement patterns characterizing each mood disorder on actigraphy compared to healthy controls.

In pre-post treatment studies, results of actigraphy suggested some treatment effects on sleep parameters captured on actigraphy. Further research linking actigraphy results to disease severity or treatment is needed to inform the clinical utility of actigraphy (Tazawa, 2019).

In 2024, we found a systematic review of eight studies (N=1,139) compared actigraphy to polysomnography for sleep stage classification in adults. Actigraphy showed moderate accuracy in distinguishing between wake and sleep states, though its ability to differentiate between specific sleep stages (light, deep, rapid eye movement) was more limited (Yuan, 2024). No policy changes are warranted.

References

On November 3, 2024, 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 “actigraphy,” “sleep studies,” “obstructive sleep apnea,” and “polysomnography.” 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

11/2016: initial review date and clinical policy effective date: 4/2017

11/2017: Policy references updated.

11/2018: Policy references updated. Policy changed from medically necessary to investigational.

11/2019: Policy references updated. Policy ID changed to CCP.1275.

11/2020: Policy references updated.

11/2021: Policy references updated.

11/2022: Policy references updated.

12/2023: Policy references updated.