Molina Clinical Policy
Actigraphy: Policy No. 374
Last Approval: 08/14/2024
Next Review Due By: August 2025

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

Actigraphy is a method for inferring sleep/wake cycles based on the magnitude of movement during sleep collected using digital devices called actigraphs. Actigraphs (or actometers or actimeters), are small, watch-shaped devices typically worn on the wrist, ankle, or trunk. They are usually worn on the non-dominant wrist and contain motion detectors (accelerometers) to monitor and record movements. The actigraph can be worn 24 hours a day for several days and collects data continuously for one week or longer. Actigraphy has been utilized for more than two decades in the study of sleep and circadian rhythms. While actigraphy may provide an estimate of total sleep time, it does not assess actual sleep or the subjective experience of sleep. Actigraphy measures sleep metrics including total sleep duration (from sleep onset to final awakening), sleep onset latency (minutes from bedtime to the first 20-minute period of sleep), total time in bed (from lights out to waking up), and sleep efficiency (ratio of total sleep duration to total time spent in bed). Movement disorders and other conditions can have an impact on actigraphy-based sleep parameters. Actigraphy is most used in patients who have suspected circadian sleep-wake phase rhythm disorders such as delayed sleep-wake disorder or shift work disorder. Actigraphy is also utilized to complement self-reported sleep duration and other sleep parameters in patients with a variety of suspected sleep disorders, as well as to document treatment response. In comparison to the gold standard of polysomnography, actigraphy does not provide estimates of sleep architecture, as information regarding the stages of non-rapid eye movement sleep and rapid eye movement sleep is typically unavailable and requires electroencephalogram, electrooculography, and electromyography. Actigraphy also does not provide information related to respiratory function. When actigraphy is compared to polysomnogram, its accuracy for total sleep time is approximately 90%, but only 55% for determining the correct sleep stage. In contrast to polysomnogram, actigraphy is unable to differentiate between the distinct phases of sleep (Thomas & Gamble 2024; Fekedulgen et al. 2020; [1]Smith et al. 2018).

Several elements have been recognized as crucial for the reliability and validity of using actigraphy to measure various sleep characteristics, including: (1) technical features of the device (e.g., tri-axial versus dual or single axis accelerometers), (2) software driven data acquisition settings (e.g., sampling rates and sensitivity settings), (3) location of device placement), (4) the mathematical algorithms used to estimate sleep/wake, (5) clinical features of the population being studied, (6) utilization of a standardized scoring approach to setting rest activity intervals, and (7) training of patients in data collection procedures. The core technology in "direct to consumer" devices may vary markedly from that accessible for therapeutic use. Current evidence is insufficient to indicate that consumer items may substitute clinical devices using validated sleep score algorithms, technologies, and processes ([1]Smith et al. 2018).

Regulatory Status

The 510(k) process of the U.S. Food and Drug Administration (FDA) has permitted the commercialization of numerous actigraphy devices (FDA product code: OLV). Some actigraphy devices are intended and marketed to track sleep-wake cycles, while others track physical activity levels.

COVERAGE POLICY

Actigraphy is considered **experimental, investigational, or unproven** when used as the sole technique to record and

analyze body movement to evaluate sleep disorders.

LIMITATIONS/EXCLUSIONS: This policy only addresses actigraphy as a stand-alone test. This does not include the use of actigraphy as a component of portable sleep monitoring. When performed as a component of portable home sleep testing, actigraphy should not be reported separately.

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 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

Current evidence evaluating actigraphy for the diagnosis of sleep disorders does not establish the effectiveness of actigraphy as a stand-alone diagnostic tool. Despite extensive application of actigraphs in sleep research and clinical settings, published literature specifically detailing the methodology for derivation of sleep parameters from the digital counts stored by actigraphs is lacking or limited as such information is critical for the appropriate analysis and interpretation of actigraphy data (Scott et al. 2020). There is also a lack of consensus in definition of sleep onset and offset, which results in inconsistent reporting of sleep parameters across studies ([2]Smith 2018). The need to address the methodologic challenges and strengths of the different actigraphic devices used for objective sleep assessment in research is recognized.

Fedele et al. (2022) completed a study of 24 participants to compare actigraphy to polysomnogram in individuals with posttraumatic amnesia. Testing was completed in a traumatic brain injury rehabilitation unit. Approximately 79.2% of participants had a severe traumatic brain injury while 20.8% had a severe traumatic brain injury. The average time post-injury was 38.2 days. Results showed a poor agreement between actigraphy and polysomnogram in determining sleep and wake parameters. Researchers noted that uncontrollable movements caused by traumatic brain injury may have impacted the data for actigraphy and recommended additional well-controlled studies to assess efficacy.

Chinoy et al. (2021) completed a study of 34 healthy young adults to assess the efficacy of consumer sleep devices (e.g., Fatigue Science Readiband, Fitbit Alta HR, Garmin Fenix 5S, Garmin Vivosmart 3, EarlySense Live, ResMed S+, SleepScore Max) compared to actigraphy and polysomnogram. Testing and reporting of results were completed following the guidelines of the Sleep Research Society. Participants were asked to stop consumption of alcohol and caffeine six days prior to testing and to establish a sleep schedule that would allow them to get a full eight hours of sleep for the four nights prior to the study. The study protocol consisted of testing on three consecutive nights using each individual's pre-study bed and wake times as their times for study. The time in bed was eight hours for each study night. The second or third night of the study consisted of an experimental sleep disruption protocol to determine the effects of fragmented sleep patterns on device algorithm performance. Results determined that most consumer sleep tracking devices were equivalent to or outperformed actigraphy.

Fekedulegn et al. (2020) noted that more comprehensive understanding of the actigraphy process and the methods used for deriving the sleep parameters from wrist movement data: 1) ensures appropriate use and interpretation of sleep parameters in future studies, 2) enables the recalibration of sleep parameters to address specific goals, and 3) inform the development of new measures and increase the breadth of sleep parameters used. The current lack of evidence-based studies and high-quality literature detailing how sleep parameters are derived results in a number of unclear variables. There is also a need to standardize sleep measures derived from actigraphy in order to facilitate communication among investigators and comparisons across studies.

Scott et al. (2020) completed a systematic review to determine the accuracy of sleep wearable devices, including actigraphy devices, in estimating sleep onset latency. It was noted that sleep wearable devices could increase the availability of applications used to measure sleep parameters. Researchers noted that "actigraphy devices produced average estimations of sleep onset latency that were often not significantly different from polysomnogram." However, the accuracy of actigraphy was noted to be dependent upon patient characteristics, such as movement disorders. It was also noted that devices measuring behavioral aspects of sleep onset consistently overestimated sleep onset latency when compared to polysomnogram.

Conley et al. (2019) conducted a meta-analysis of 96 studies in adults with and without chronic conditions that concluded that actigraphy overestimated total sleep time (by 11.2 minutes in healthy adults and by 22.4 min in adults with chronic conditions), and sleep efficiency (by 1.9% in healthy adults and by 5.2% in those with chronic conditions) compared to polysomnogram. Differences were statistically significant only among those with chronic conditions.

Smith et al. ([1]2018) conducted a systematic review and meta-analysis of 81 studies commissioned by the American Academy of Sleep Medicine regarding the clinical utility of actigraphy versus sleep logs andpolysomnogram for evaluating a range of sleep disorders. The meta-analysis yielded findings broadly consistent with those of Conley et al. (2019). The study concluded substantial evidence that actigraphy underestimates sleep onset latency and wake after sleep onset compared to polysomnogram, and that these differences are clinically meaningful.

An et al. (2020) completed a systematic review and meta-analysis to assess the utility of actigraphy in chronic pain patients. Studies using actigraphy to measure sleep in chronic pain patients were searched in databases and included 34 with 3,590 patients. Sleep parameters measured by actigraphy were compared with those measured by sleep diary and polysomnogram. No differences were noted between actigraphic and polysomnogram in sleep parameters; however, due to the limited number of studies and large variability, it was not established that the two are equivalent objective measures. Based on thresholds set by the 2018 American Academy of Sleep Medicine on actigraphy, the analysis noted that the 95% confidence interval of the mean differences in the study were large and suggested that the two methods (actigraphy and polysomnogram) cannot be used interchangeably ([1]Smith et al. 2018). Therefore, while no significant differences were found, it is not definitive that the two measurement methods are consistent and produce the same measurements. The authors concluded that while actigraphy presents many potential advantages, further research is required to compare the different assessment methods with large RCTs measuring sleep using multiple assessment methods in chronic pain patients.

National and Specialty Organizations

The **European Insomnia Guideline** published updated recommendations for the evaluation of insomnia. The guidelines include the following recommendations for actigraphy (Riemann et al. 2023):

- "In case of clinical suspicion of irregular sleep-wake schedules or circadian rhythm sleep-wake disorders (Grade A recommendation).
- In case of clinical suspicion of periodic leg movements in sleep (Grade A recommendation).
- To assess quantitative rest activity (Grade A recommendation) and sleep parameters (Grade C recommendation)."

The guidelines further state that actigraphy **cannot** "differentiate patients with insomnia from good sleepers…[and] does not deliver a valid estimation of sleep stages like the polysomnogram."

The **American Academy of Sleep Medicine (AASM)** clinical practice guidelines for actigraphy established recommendations for the use of actigraphy in adult and pediatric patients with suspected or diagnosed sleep disorders or circadian rhythm sleep-wake disorders. These guidelines only apply to the use of FDA-approved devices and make the following recommendations for the use of actigraphy ([2]Smith et al. 2018):

- Only one **strong** recommendation was issued which recommends that clinicians not use actigraphy in place of electromyography for the diagnosis of periodic limb movement disorder in adult and pediatric patients.
- To estimate sleep parameters in adult patients with insomnia disorder. (Conditional)
- In the assessment of pediatric patients with insomnia disorder. (Conditional)
- In the assessment of adult patients with circadian rhythm sleep-wake disorder. (Conditional)
- In the assessment of pediatric patients with circadian rhythm sleep-wake disorder. (Conditional)
- Integrated with home sleep apnea test devices to estimate total sleep time during recording (in the absence of alternative objective measurements of total sleep time) in adult patients suspected of 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)

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Code

Code	Description
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)

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

08/14/2024	Policy reviewed, no changes to criteria. Updated Overview, Summary of Medical Evidence, and References. Examples removed from clinical criteria but remains investigational and experimental.
08/09/2023	Policy reviewed, no changes to criteria. Updated Overview, Summary of Medical Evidence, and References sections. IRO Peer Review on June 28, 2023, by a practicing, board-certified physician with a specialty in Sleep Medicine.
08/10/2022	Policy reviewed and updated. No changes in coverage position. Updated references.
08/11/2021	Policy reviewed. No changes in coverage position. Updated references.
09/16/2020	New policy. IRO Peer Review. 7/15/2020. Practicing physician board certified in Psychiatry, Psychiatry Child & Adolescent, Sleep Medicine.

REFERENCES

1. An D, Selvanathan J, Wong J, et al. The utility of actigraphy to measure sleep in chronic pain patients and its concordance with other sleep measures: A systematic review and meta-analysis. J Sleep Disord Ther. 2020 Apr 3;9(2). doi: 10.35248/2167-0277.19.9.308.
2. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database: National coverage determination (NCD) – Sleep testing for obstructive sleep apnea (OSA) (240.4.1). Effective Date May 3, 2009. https://www.cms.gov/medicare-coverage-database/search.aspx.
3. Chinoy ED, Cuellar JA, Huwa KE, et al. Performance of seven consumer sleep-tracking devices compared with polysomnography. Sleep. 2021 May 14;44(5): zsaa291. doi: 10.1093/sleep/zsaa291. PMID: 33378539; PMCID: PMC8120339.
4. Conley S, Knies A, Batten J, Ash G, Miner B, Hwang Y, Jeon S, Redeker NS. Agreement between actigraphic and polysomnographic measures of sleep in adults with and without chronic conditions: A systematic review and meta-analysis. Sleep Med Rev. 2019 Aug; 46:151-160. doi: 10.1016/j.smrv.2019.05.001. Epub 2019 May 13. PMID: 31154154; PMCID: PMC6594867.
5. Fedele B, McKenzie D, Williams G, et al. A comparison of agreement between actigraphy and polysomnography for assessing sleep during posttraumatic amnesia. J Clin Sleep Med. 2022 Nov 1;18(11):2605-2616. doi: 10.5664/jcsm.10174. PMID: 35912692; PMCID: PMC9622995.
6. Fekedulegn D, Andrew ME, Shi M, et al. Actigraphy-Based Assessment of Sleep Parameters. Ann Work Expo Health. 2020 Apr 30;64(4):350-367. doi: 10.1093/annweh/wxaa007. PMID: 32053169; PMCID: PMC7191872.
7. Riemann D, Espie CA, Altena E, et al. The European Insomnia Guideline: An update on the diagnosis and treatment of insomnia 2023. J Sleep Res. 2023 Dec;32(6): e14035. doi: 10.1111/jsr.14035. PMID: 38016484.
8. Scott H, Lack L, Lovato N. A systematic review of the accuracy of sleep wearable devices for estimating sleep onset. Sleep Med Rev. 2020 Feb; 49:101227. doi: 10.1016/j.smrv.2019.101227. Epub 2019 Nov 6. PMID: 31901524.
9. [1]Smith MT, McCrae CS, Cheung J, et al. Use of actigraphy for the evaluation of sleep disorders and circadian rhythm sleep-wake disorders: An American Academy of Sleep Medicine systematic review, meta-analysis, and grade assessment. J Clin Sleep Med. 2018 Jul 15;14(7):1209-1230. doi: 10.5664/jcsm.7228. PMID: 29991438; PMCID: PMC6040804.
10. [2]Smith MT, McCrae CS, Cheung J, et al. Use of Actigraphy for the Evaluation of Sleep Disorders and Circadian Rhythm Sleep-Wake Disorders: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2018 Jul 15;14(7):1231-1237. doi: 10.5664/jcsm.7230. PMID: 29991437; PMCID: PMC6040807.
11. Thomas SJ, Gamble K. Actigraphy in the evaluation of sleep disorders. Updated March 14, 2024. Accessed June 5, 2024. www.uptodate.com/
12. United States Food and Drug Administration (FDA). 510(k) premarket notification database. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm