Molina Clinical Policy
Actigraphy: Policy No. 374
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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 wrist movement collected using digital devices called actigraphs. Actigraphy has been utilized for more than two decades in the study of sleep and circadian rhythms (Fekedulegn et al. 2020). It measures the movement of a limb, and while it may provide an estimate of total sleep time, it does not assess actual sleep or the subjective experience of sleep. The actigraphy device includes a small accelerometer that monitors and records the occurrence and degree of motion. 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 up to a period of one week or longer. 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). Actigraphy is most commonly 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 (Thomas & Gamble 2022). The devices are typically worn on the wrist or ankle for sleep applications. The optimal placement location for the actigraph to obtain the most accurate data is still a matter of debate. Based on observations that the wrist may detect more movement than the ankle and trunk and that placement on the dominant arm detects more movement than placement on the nondominant arm, the device is generally worn on the nondominant wrist in the majority of studies.

Fekedulegn et al. (2020) noted that although the methodology of actigraphy assessed in many studies is ”based on a specific actigraphic device and associated sleep/wake algorithms, the overall methodological process is transferable to other devices and sleep scoring functions.” Furthermore, it should be noted that actigraphy does not directly measure sleep but rather movement, which is then used to estimate sleep/wake cycles (Thomas & Gamble 2022). Actigraphy primarily involves direct measurement of movement and indirect assessment of sleep via the use of specific algorithms (Thomas & Gamble 2022). As a result, movement disorders and other conditions can have an impact on actigraphy-based sleep parameters (Thomas & Gamble 2022).

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 (Smith et al. 2018a).

Current peer-reviewed publications state the following regarding actigraphy:
- Actigraphy has been validated in a variety of populations (Smith 2018b)

- In comparison to the gold standard of polysomnography (PSG), actigraphy does not provide estimates of sleep architecture, as information regarding the stages of non-rapid eye movement sleep and rapid eye movement (REM) sleep is typically unavailable and requires electroencephalogram (EEG), electrooculography, and electromyography. Actigraphy also does not provide information related to respiratory function (Smith 2018a).
- Actigraphy is accurate at identifying periods of sleep but less accurate at identifying sleep onset and periods of wakefulness during sleep. When actigraphy is compared to PSG, its accuracy for total sleep time is approximately 90%, but only 55% for determining the correct sleep stage. In contrast to PSG, actigraphy is unable to differentiate between the distinct phases of sleep (Thomas & Gamble 2022).
- Actigraphy generally overestimates total sleep time and sleep efficiency, owing to the difficulty of delineating sleep onset, which results in an overestimation of sleep time in situations where patients lie in bed relatively motionless (e.g., patients with insomnia, those who lie in bed watching television, older adults in a nursing home environment). Actigraphy, on the other hand, may underestimate sleep in patients with a movement disorder (Thomas & Gamble 2022).
- Actigraphy is not a substitute for PSG when EEG is required to define sleep architecture, sleep stage, aberrant movements during sleep, or sleep-related respiratory issues are suspected (Thomas & Gamble 2022).

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, including but not limited to the following uses to evaluate sleep disorders:

- Detection of seizures during sleep
- Diagnosis of hypertension
- Diagnosis of sleep disorders (e.g., periodic limb movements of sleep and sleep-wake disturbance)
- Evaluation of depression
- Evaluation of disruptive mood dysregulation disorder
- Evaluation of motor fluctuations in persons with Parkinson's disease
- Evaluation of post-traumatic stress disorder
- In the setting of opioid detoxification
- Screening for idiopathic REM sleep behavior disorder

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.

High quality medical studies do not indicate that actigraphy performs as well as, or better than, the conventional methods of determining sleep-wake cycles. Evidence demonstrating that actigraphy provides a reliable measure of sleep efficiency is lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 is limited and 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 (Smith 2018b).

The need to address the methodologic challenges and strengths of the different actigraphic devices used for objective sleep assessment in research is recognized. 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 PSG." 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 PSG.

Agreement Between Actigraphic and Polysomnographic Measures of Sleep in Adults with and Without Chronic Conditions: A Systematic Review and Meta-Analysis (2019)

A meta-analysis of 96 studies in adults with and without chronic conditions conducted by Conley et al. (2019) 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 PSG. Differences were statistically significant only among those with chronic conditions.

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

The Utility of Actigraphy to Measure Sleep in Chronic Pain Patients and Its Concordance with Other Sleep Measures: A Systematic Review and Meta-Analysis (2020)

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 PSG. No differences were noted between actigraphic and PSG 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% CI of the mean differences in the study were large and suggested that the two methods (actigraphy and PSG) cannot be used interchangeably (Smith et al. 2018a). 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

American Academy of Sleep Medicine (AASM)

AASM (Smith et al. 2018a; Smith et al. 2018b) 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.

AASM made the following recommendations in these guidelines, which included a systematic review of the evidence:

- The following are **conditional** recommendations for the use of actigraphy:
  - 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)
- 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.

Conditional recommendations reflect a lower degree of certainty regarding the outcome and appropriateness of the patient care strategy for all patients. A strong recommendation is one that clinicians should follow under most circumstances.

SUPPLEMENTAL INFORMATION

Polysomnography (PSG): PSG is the gold standard for the diagnosis, assessment, and management of sleep disorders, including obstructive sleep apnea. As the name suggests, it is an electrophysiological recording of multiple parameters, including an EEG, a chin electromyogram, and an electrooculogram which help to score various sleep stages. Sleep parameters include:

- *Sleep efficiency (SE)* is a measure that is closely related to PSLP. SE is estimated in similar fashion to PSLP, except that it is defined using data from the SLP ('O–O' interval) rather than TIB. Therefore, SE is defined as the percentage of time spent asleep during the SLP (between onset of persistent sleep and sleep offset).
- *Sleep onset latency* refers to the number of minutes it took a subject to fall asleep. It is the number of minutes between lying down in bed and actually falling asleep. Theoretically, it is the number of minutes from the time the subject reported going to bed (in bedtime) to the time the subject was first scored as asleep by the algorithm.
- *Wake after sleep onset* is the number of minutes a participant was awake between sleep onset and sleep offset (O–O interval). The criterion used for defining the two time points (sleep onset and sleep offset) affects the estimate of this parameter. The value considered normal in adults is <10% of total sleep minutes or 42 min for a person who sleeps 7 hours/night.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

CPT	Description
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording) NOTE: Code used for stand-alone actigraphy testing only (This code does not apply to other sleep testing monitors that include the use of actigraphy as component of portable sleep monitoring. When used as a component of portable sleep monitoring, actigraphy should not be separately reported). Actigraphy testing is considered experimental and investigational under the Plan when utilized as a stand-alone procedure for the diagnosis, evaluation, and/or management of sleep disorders or for any other indication.

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

8/09/2023	Policy reviewed, no changes to criteria. Updated Overview, Summary of Medical Evidence, and References sections. Grammatical edits to Disclaimer section and Documentation Requirements disclaimer. IRO Peer Review on June 28, 2023, by a practicing, board-certified physician with a specialty in Sleep Medicine.
8/10/2022	Policy reviewed and updated. No changes in coverage position. Updated references.
8/11/2021	Policy reviewed. No changes in coverage position. Updated references.
9/16/2020	New policy. IRO Peer Review. 7/15/2020. Practicing physician board certified in Psychiatry, Psychiatry Child & Adolescent, Sleep Medicine.

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