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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.

RECOMMENDATION

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 rapid eye movement (REM) sleep behavior disorder

Note: 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 perfroms 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.

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Actigraphy, a method for inferring sleep/wake cycles based on magnitude of wrist movement collected using digital devices called actigraphs, has been used for over two decades in studies of sleep and circadian rhythms (Fekedulegn et al. 2020). It measures movement of a limb, and although it may provide an estimate of total sleep time, it does not actually measure 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, also called actometers or actimeters, is a small watch-shaped devices that are generally placed on the wrist, ankle or trunk and are usually worn on the non-dominant wrist and contain motion detectors (accelerometers) to monitor and record movements (Ancoli-Israel et al., 2003). The actigraph can be worn 24 hours a day for many days, and it captures data continuously over an extended period of one week or longer.

Actigraphy records sleep parameters such as total sleep duration (from sleep onset to final waking), sleep onset latency (minutes from bedtime to the first 20-minute period of sleep), total time in bed (from lights out to got out of bed events), and sleep efficiency (ratio of total sleep duration to total time spent in bed). The most common use of actigraphy is in patients with suspected circadian sleep-wake phase rhythm disorders such as delayed sleep-wake disorder or shift work disorder. Actigraphy is also used to complement self-reported sleep duration and other sleep parameters in patients with a range of suspected sleep disorders and to document response to treatment. (Thomas SJ, 2020). For sleep applications, the devices are usually worn on the wrist or ankle. The best placement site for the actigraph to obtain the most reliable data remains controversial. In most studies, the device is generally worn on the nondominant wrist based on observations that wrist may detect more movements compared with the ankle and trunk, and that placement on the dominant arm detects more movement than the nondominant arm.

Fekedulegn et al. noted that while 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 generalizable to other devices and sleep scoring functions (Fekedulegn et al. 2020).' Furthermore, it should be recognized that actigraphy does not directly measure sleep (Sadeh, 2011) but rather measures movement, which is then used to estimate sleep/wake cycles. Actigraphy, essentially, involves direct measurement of movement and indirect assessment of sleep through the use of specific algorithms (de Souza et al., 2003; Natale et al., 2014). Therefore, actigraphy-based sleep parameters can be affected by movement disorders and other conditions.

Several factors have been identified as significant for the reliable and valid use of actigraphy to measure certain sleep parameters, including: (1) technical features of the device (eg, tri-axial versus dual or single axis accelerometers); (2) software driven data acquisition settings (eg, sampling rates and sensitivity settings); (3) location of device placement (Zinkhan M, 2014); (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. It should be noted that the basic technology in products sold "direct to consumers" may differ significantly from what is available for clinical application. Current data are not adequate to suggest that consumer products can be used as a replacement for clinical devices using validated sleep scoring algorithms, technologies, and procedures (American Academy of Sleep Medicine Systematic Review, Meta-Analysis, and GRADE Assessment, 2018)

- Actigraphy has been validated in a variety of populations (AASM 2007, 2018).
- Compared with a gold standard of polysomnography, actigraphy does not provide estimates of sleep architecture, as information related to the staging of non-rapid eye movement (NREM) sleep and rapid eye movement (REM) sleep is generally not available, and requires electroencephalogram (EEG), electrooculography (EOG), and electromyography (EMG). Similarly, actigraphy does not provide information related to respiratory function (AASM, Meta-Analysis, and GRADE Assessment 2018).
- While actigraphy is accurate for identifying periods of sleep, it is less accurate for identifying sleep onset and periods of wakefulness during sleep compared to the gold standard of polysomnography (PSG). In comparison to PSG, the accuracy of actigraphy is approximately 90% for total sleep time but only 55% for determining the correct sleep stage (Thomas, SJ; UpToDate 2020). In comparison with PSG, another limitation is that actigraphy is not able to identify stages of sleep.
- Actigraphy generally overestimates total sleep time and sleep efficiency, mainly because the delineation of sleep onset is difficult and results in overestimation of sleep time in situations in which 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). Conversely, actigraphy may underestimate sleep in patients with a movement disorder (Thomas, SJ; UpToDate 2020).
- Actigraphy is not a replacement for PSG when electroencephalography is needed to characterize sleep architecture, sleep stage, or abnormal movements during sleep, or when sleep-related breathing disorders are suspected.

Regulatory Status

Numerous actigraphy devices have been cleared for marketing by the U.S. Food and Drug Administration 510(k) process. Some actigraphy devices are designed and marketed to measure sleep-wake states while others to measure levels of physical activity.

SUMMARY OF MEDICAL EVIDENCE

Current evidence evaluating actigraphy for the diagnosis of sleep disorders is very limited and does not establish the effectiveness of actigraphy as a stand-alone diagnostic tool.

Actigraphy tends to overestimate sleep compared to PSG in general (Van de Water et al., 2011). Despite the high rate of agreement between PSG and actigraphy in healthy subjects with normal sleep patterns (Sadeh, 2011), the rate of agreement is lower in those with poor sleep quality. This is primarily due to the low specificity of the sleep/wake scoring algorithms since immobile wakefulness is often scored as sleep (Lichstein et al., 2006).

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 (Ancoli et al. 2003; Natale et al., 2009; Meltzer et al., 2012; Fawkes et al., 2015). There is also a lack of consensus in definition of sleep onset and offset, which results to inconsistent reporting of sleep parameters across studies (AASM 2018; Berger et al., 2005;).

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.

Systematic Review and Meta-Analysis

Leg Actigraphy to Quantify Periodic Limb Movements of Sleep: A Systematic Review and Meta-Analysis (2014)

Significant heterogeneity from a limited number of studies in terms of type of actigraph utilized, position of the device on the lower extremity and methods employed to count periodic limb movements of sleep (PLMS) was concluded from a systematic review and meta-analysis on the use of leg actigraphy to diagnose PLMS (Plante et al. 2014). Common accelerometers differ in sensitivity and specificity to detect PLMS and is likely related to the technical specifications of a particular device. A significant barrier to the use of actigraphs in clinical settings is the inability to combine data from the actigraphs placed on both legs. Additional research is necessary to determine the optimal methods to quantify PLMS using leg actigraphy, in addition to specific clinical situations in which these devices may prove most beneficial.

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 at al. in 2019 concluded that actigraphy overestimated total sleep time (by 11.2 min 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 (Conley et al., 2019).

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. In a review of 81 studies, the authors concluded substantial evidence that actigrahy underestimates sleep onset latency (SOL) and wake after sleep onset (WASO) compared to PSG, and that these differences are clinically meaningful (Smith et al., 2018).

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)

A systematic review and meta-analysis aimed assessed the utility of actigraphy in chronic pain patients (An D, et al. 2020). Studies using actigraphy to measure sleep in chronic pain patients were searched in databases and included 34 with 3,590 patients. Meta-analyses were also conducted to compare sleep parameters measured by actigraphy with those measured by sleep diary and PSG. The meta-analyses, using the random effects model, were conducted to examine the concordance of actigraphy versus sleep diary and actigraphy versus PSG for commonly measured sleep parameters. 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 suggests that the two methods (actigraphy and PSG) cannot be used interchangeably (AASM Systematic Review, Meta-Analysis, and GRADE Assessment. Journal of Clinical Sleep Medicine, 2018). Thus 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.

<u>American Academy of Sleep Medicine (AASM)</u>

According to the updated AASM Practice Parameters for the Use of Actigraphy in the Assessment of Sleep and Sleep Disorders, actigraphy is increasingly used in sleep research and the clinical care of patients with sleep and circadian rhythm abnormalities (Morgenthaler, et al., 2007). The practice parameters state that actigraphy provides a reasonably accurate estimate of sleep patterns in normal, healthy adult populations and in patients suspected of certain sleep disorders. The practice parameters address the use of actigraphy in patients with advanced sleep phase syndrome, delayed sleep phase syndrome, shift work disorder, jet-lag, and non-24 hour sleep/wake syndrome. Regarding OSA, the AASM practice parameters state that, when PSG is not available, actigraphy is indicated as a method to estimate total sleep time in patients with OSA, and that combined with a validated way of monitoring respiratory events, use of actigraphy may improve accuracy in assessing the severity of OSA compared to using time in bed. The practice parameters recommend additional research to compare results from different actigraphy devices and the variety of algorithms used to evaluate data in order to further establish standards of actigraphy technology, and notes that additional study addressing the reliability and validity of actigraphy compared to reference standards such as PSG is needed.

AASM (2008) practice parameters evaluated the clinical management of chronic insomnia in adults and noted that actigraphy is indicated as a method (option) to characterize circadian rhythm patterns or sleep disturbances in individuals with insomnia, including insomnia associated with depression.

AASM (2018) practice guidelines for actigraphy established clinical practice recommendations for the use of actigraphy in adult and pediatric patients with suspected or diagnosed sleep disorders or circadian rhythm sleep-wake disorders, and only apply to the use of FDA-approved devices. A strong recommendation was issued that 'Clinicians not use actigraphy in place of electromyography for the diagnosis of periodic limb movement disorder in adult and pediatric patients' was issued.

DEFINITIONS

Polysomnography (PSG): The gold standard for evaluating sleep disorders. As the name suggests, it is an electrophysiological recording of multiple parameters, including an electroencephalogram (EEG), a chin electromyogram (EMG), and an electrooculogram which help to score various sleep stages.

Sleep Parameters

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 (SOL) 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 bed time) 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 h/night.

CODING INFORMATION

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is covered or non-covered. coverage is determined by the benefit document. this list of codes may not be all inclusive.

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

HCPCS	Description

ICD-10	Description: [For dates of service on or after 10/01/2015]

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Government Agency

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National coverage determination (NCD) Search. Accessed at: http://www.cms.gov/medicare-coverage-database/

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Professional Society Guidelines and Other Publications

American Academy of Sleep Medicine

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Revision/Review History:
9/16/20: New Policy. Peer Review: Policy reviewed by IRO practicing physician board-certified in Psychiatry, Psychiatry Child & Adolescent, Sleep Medicine. 7/15/2020

8/11/21: Annual Review. No coverage criteria changes or notable revisions with this annual review.

**Annual Reviews/Policy Revisions: All content, clinical evidence, coverage criteria, practice guidelines, appendices and reference sections were reviewed and revised with the most recent medical literature and available evidence. Coverage criteria for Initial and Continuation of Therapy revised/updated as appropriate.*