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Medical Policy Manual Medicine, Policy No. 125

Actigraphy

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Actigraphy is used to record and analyze body movement, including but not limited to its use to evaluate sleep disorders.

MEDICAL POLICY CRITERIA

Actigraphy is considered **investigational** as a technique to record and analyze body movement, including but not limited to its use to evaluate sleep disorders.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

Actigraphy refers to the assessment of activity patterns and levels of physical activity by devices used to record body movement. The information is interpreted by computer algorithms as periods of sleep (absence of activity) and wake (activity). Sleep/wake cycles may be altered in sleep disorders including insomnia, circadian rhythm sleep disorders, sleep-related

breathing disorders, restless legs syndrome, and periodic limb movement disorder. In addition, actigraphy could potentially be used to assess sleep/wake disturbances associated with numerous other diseases or disorders such as attention-deficit/hyperactivity disorder, chronic fatigue syndrome, asthma, Parkinson's syndrome, post-surgical delirium, stroke, advanced cancer, and intensive care monitoring.

Actigraphy has been used for over two decades as an outcome measure in sleep disorders research (i.e., insomnia, circadian rhythm disorders, sleep-related breathing disorders, restless leg syndrome, and periodic limb movement disorder). Actigraphy devices are typically placed on the nondominant wrist and are worn continuously for at least 24 hours. The activity monitors may also be placed on the ankle for the assessment of restless leg syndrome, or on the trunk to record movement in infants. Activity is usually recorded for three days or more, and can be collected continuously over extended time periods with regular downloading of data onto a computer for display and analysis. The algorithms for detection of movement are variable among devices and may include "time above threshold," the "zero crossing method," or digital integration" method, resulting in different sensitivities. The digital integration method reflects both acceleration and amplitude of movement; this form of data analysis may be most commonly used today. Data on patient bed times (lights out) and rise times (lights on) are entered into the record from daily patient sleep logs or by patient-activated event markers. Proprietary software is then used to calculate periods of sleep based on the absence of detectable movement along with movement-related level of activity and periods of wake. In addition to providing graphic depiction of the activity pattern, device-specific software may analyze and report a variety of sleep parameters including sleep onset, sleep offset, sleep latency, total sleep duration and wake after sleep onset.

REGULATORY STATUS

Numerous actigraphy devices have received U.S. Food and Drug Administration (FDA) approval through the 510(k) process. Some actigraphy devices are designed and marketed to measure sleep/wake states while others are designed and marketed to measure levels of physical activity. Food and Drug Administration product code: OLV.

EVIDENCE SUMMARY

This policy was initially based primarily on 2003 practice parameters issued by the American Academy of Sleep Medicine (AASM)[1] (See the Clinical Practice Guidelines section below).

Subsequent literature reviews focused on randomized studies comparing the results of actigraphy with the following:

- Polysomnography (PSG): to determine whether actigraphy could be considered an alternative to PSG.
- Other methods such as sleep diaries or direct observation: to determine whether actigraphy could provide incremental information that would result in an improvement in patient management.

Actigraphy is frequently used as an intermediate outcome in research studies, but there were no randomized controlled trials identified that focused on the use of actigraphy to either diagnose or direct the management of patients with sleep disorders. For example, actigraphy has been used as an intermediate outcome in several trials of melatonin for sleep disturbances in patients with Alzheimer's disease[2-5] or other drug trials.[6]

The clinical validity of actigraphy depends, to a large extent, on the modality with which it is being compared.

Comparisons with sleep diaries show reasonable correlations for measures of bedtime, sleep onset, and wake time in adults but not in adolescents. The relative and unique contributions of actigraphy and sleep logs in the diagnosis of sleep disorders and measurement of treatment effects remains to be demonstrated.

Comparisons with the more resource-intensive PSG or behavioral scoring indicate that, with the appropriate sensitivity threshold, actigraphy has sufficient sensitivity to detect sleep but has poor specificity in distinguishing between wake and sleep. The literature also indicates that the accuracy of actigraphy to differentiate between wake and sleep decreases as the level of sleep disturbance increases in patients with insomnia.

The following article summaries are representative of currently published studies of actigraphy used in adults and children for a variety of conditions.

ADULTS

Systematic Review

A systematic review of leg actigraphy to quantify periodic limb movements of sleep (PLMS) found significant heterogeneity for the sensitivity and specificity of different devices.[7] Factors contributing to the heterogeneity were variability in devices tested, placement of the devices (e.g., foot or ankle), thresholds to define clinically significant PLMS (e.g., 5, 10, or 15/hour), and algorithms used to calculate the periodic limb movements. The inability to combine actigraphy data from both legs also presents a limitation for clinical use at this time.

Nonrandomized Studies

Paquet (2007) compared actigraphic assessment of sleep and wake with PSG under varying conditions of sleep disturbance (night time sleep, daytime sleep, daytime sleep with caffeine) in 23 healthy subjects.[8] Data were analyzed from a study that evaluated the effects of caffeine on daytime recovery sleep. The experimental protocol involved two visits to the sleep laboratory, each including one night of nocturnal sleep, one night of sleep deprivation, and the next day of recovery sleep (once with placebo and once with 200 mg caffeine). The Actiwatch® and PSG equipment were synchronized prior to recording, and assessment of sleep and wake were compared for each 1-minute interval to evaluate sensitivity, specificity, and accuracy of actigraphy in comparison with manually staged sleep from PSG recordings. Sensitivity was defined as the proportion of all epochs scored as sleep by PSG that were also scored as sleep by actigraphy. Specificity was the proportion of all epochs scored as wake by PSG that were also scored as wake by actigraphy. Accuracy was the proportion of all epochs correctly identified by actigraphy. Four different sensitivity settings/scoring algorithms were compared. In general, as the threshold to detect movement was raised, sensitivity to detect sleep increased, but the ability to detect wake (specificity) decreased. With the medium threshold algorithm, the sensitivity to detect sleep was 95–96%. However specificity, or the ability to detect wake, was 54% for night time sleep, 45% for daytime recovery sleep, and 37% for daytime recovery sleep with caffeine. A main finding of the study was that the more disturbed the sleep, the less the actigraphy was able to differentiate between true sleep and quiet wakefulness, with an accuracy of 72% for the most disrupted sleep condition. Through

experimental manipulation of the level of sleep disturbance, this study provides substantial information about the limitations of this technology for clinical populations with sleep disruption.

Several studies assessed clinical validity in patients with primary or secondary sleep disorders. One study assessed the sensitivity and specificity of actigraphy in comparison with PSG in older adults treated for chronic primary insomnia.[9] Visual scoring of the PSG data was blinded and actigraphic records were scored by proprietary software. The study found that actigraphy agreed with PSG scoring of sleep for 95% of the 30-second epochs (sensitivity), but agreed with PSG scoring of wake only 35% of the time (specificity). The authors conclude that, "the clinical utility of actigraphy is still suboptimal in older adults for chronic primary insomnia."

Kaplan (2012) compared outcomes from actigraphy, PSG, and sleep diary in 27 patients with bipolar disorder who were between mood episodes and in 27 age- and sex-matched controls.[10] Actigraphic and PSG measures of total sleep time were highly correlated, but correlations were marginal for sleep onset latency and wake after sleep onset. Sensitivity and specificity were not assessed. Blinded evaluation found no significant difference in sleep parameters between patients with bipolar disorder who were between mood episodes and controls.

Beecroft (2008) reported an observational study of sleep monitoring in the intensive care unit, comparing nurse assessment, actigraphy, and PSG, in 12 stable, critically ill, mechanically ventilated patients.[11] PSG showed severely disrupted sleep, with decreased total sleep time and sleep efficiency, high frequency of arousals and awakenings (fragmentation), and abnormal sleep architecture (decreased slow wave and rapid eye movement [REM] sleep). Both the nurse's and the actigraphic assessment of sleep were found to be inaccurate. Actigraphy overestimated the total sleep time, with a median that was 2–3 hours greater than PSG. Median sleep efficiency (actual sleep as a percentage of total recording time) was estimated at 61–95% by actigraphy, depending on the sensitivity setting, which was substantially higher than the 42% median sleep efficiency shown by PSG with sleep staging.

Actigraphy with a SOMNOwatch™ in patients (n=28) with sleep-disordered breathing showed a sensitivity of 90%, a specificity of 95%, and overall accuracy of 86% in comparison with PSG.[12] Correlations were high for total sleep time (0.89), sleep period time (0.91), and sleep latency (0.89) and moderate for sleep efficiency (0.71) and sustained sleep efficiency (0.65).

Studies continue to assess different modes of data collection and analysis, including varying the sensitivity settings for existing algorithms and developing new scoring algorithms. A 2011 publication compared three collection modes (proportional integration, time above threshold, and zero crossings) with PSG in 889 older community-dwelling men who participated in the Outcomes of Sleep Disorders in Men (MrOS) study.[13] The proportional integration mode was found to correspond best to PSG, with moderate interclass correlation coefficients of 0.32 to 0.57. Actigraphy in this mode overestimated total sleep time by an average of 13.2 minutes, with an absolute difference (positive or negative direction) of 52.9 minutes. There was a systematic bias for overestimating total sleep time which increased with decreasing sleep duration.

In 233 adult patients, Crespo (2013) studied the differences between ambulatory blood pressure monitoring (ABPM) parameters obtained using three different methods; fixed schedule, diary, and actigraphy-based automatic algorithm.[14] Statistically significant differences were found both individually and for the group. For individuals, the differences in measurements could result in different classification of cardiovascular risk and, therefore,

different diagnosis and treatment. The authors reported better individual accuracy with the automatic algorithm based on actigraphy compared with diaries and fixed schedule, from which actual activities could differ. This study did not go on to determine whether treatment plans actually changed or if overall health outcomes were impacted.

Marino (2013) assessed clinical validity of wrist actigraphy to measure nighttime sleep compared to polysomnography (PSG) using the Cole-Kripke algorithm in 54 young and older adults, either healthy or with insomnia, and in 23 night-workers during daytime sleep.[15] Actigraphy comparison with PSG showed a sensitivity (ability to detect sleep, 97%) and accuracy (86%) during the usual sleep/lights-out period to be high, but specificity (ability to detect wake, 33%) was low. Actigraphy underestimated the amount of wake when wake after sleep onset increased.

Taibi (2013) found a sensitivity of 96.1% and specificity of 36.4% in a study of 16 older adults with insomnia who underwent 8 nights of concurrent actigraphy and PSG.[16] Sleep efficiency was overestimated by actigraphy (84.4%) compared with PSG (66.9%) and the accuracy of actigraphy declined as sleep efficiency declined.

Levenson (2013) evaluated the utility of sleep diaries and actigraphy to differentiate older adults with insomnia (n=79) from good sleeper controls (n=40).[17] Sensitivity and specificity were determined for sleep onset latency, wake after sleep onset, sleep efficiency, and total sleep time. Using receiving operating characteristic curve analysis, sleep diary measurements produced areas under the curves in the high range (0.84-0.97), whereas actigraphy performed less well at discriminating between older adults with insomnia and controls (area under curves 0.58-0.61).

Additional, nonrandomized studies[18] have been identified which assess the use of actigraphy to measure sleep behavior or to diagnose a variety of conditions; however, conclusions are limited as these studies do not compare actigraphy with standard of care sleep measures, such as a sleep diary.

CHILDREN AND ADOLESCENTS

Systematic Review

There were no systematic reviews identified.

Nonrandomized Studies

Toon (2016) compared accelerometer devices against polysomnography (PSG) and actigraphy in a sample of 78 children and adolescents (65% male, mean age 8.4 ± 4.0 y) with suspected sleep disordered breathing.[19] Actigraphy overestimated sleep onset latency (SOL) by 21 min; no differences between PSG and actigraphy were found in mean total sleep time (TST), wake after sleep onset (WASO), and sleep efficiency (SE). However, the authors found larger discrepancy in actigraphy to PSG the shorter and more fragmented the sleep. The authors state this cohort of children is not generalizable to the non-snoring pediatric population, and another limitation is that data were only collected for one night – previous studies have reported actigraphy assessment requires at least five nights of recording to ensure reliability.

Werner (2008) assessed agreement between actigraphy and parent diary or questionnaire for sleep patterns in 50 children, aged 4–7 years, recruited from kindergarten schools in

Switzerland. Sixty-eight families agreed to participate of 660 families invited (10%).[20] Each child was home-monitored with an actigraph for 6 to 8 consecutive nights, and parents were requested to complete a detailed sleep diary (15-minute intervals) during the monitoring days to indicate bedtime, estimated sleep start, wake periods during the night, and estimated sleep end. Parent's assessment of habitual wake time, get up time, bedtime, time of lights off, sleep latency, and nap duration were obtained through questionnaire. Satisfactory agreement, defined a priori as differences smaller than 30 minutes, was achieved between actigraphy and diary for sleep start, sleep end, and assumed sleep. Actual sleep time and nocturnal wake time differed by an average of 72 minutes and 55 minutes, respectively. Satisfactory agreement was not reached between actigraphy and questionnaire for any of the parameters. The authors concluded that the diary is a cost-effective and valid source of information about children's sleep-schedule time, while actigraphy may provide additional information about nocturnal wake time or may be used if parents are unable to report in detail. Compliance and accuracy in the diaries is likely to be affected by the motivation of the parents, who in this study were self-selected.

In 2010, O'Driscoll reported a comparison of actigraphy with PSG in 130 children who had been referred for assessment of sleep-disordered breathing.[21] The arousal index and apnea-hypopnea index (AHI) scored from PSG were compared to the number of wake bouts/hour and actigraphic fragmentation index. Using a PSG-determined AHI of greater than 1 event/hour, the actigraphic measure of wake bouts/hour had a sensitivity and specificity of 14.9% and 98.8%, respectively, and the fragmentation index had a sensitivity and specificity of 12.8% and 97.6%, respectively. Using a PSG-determined arousal index greater than ten events per hour as the reference standard, the actigraphic measure of wake bouts/hour had a sensitivity and specificity of 78.1% and 52.6% and the fragmentation index had a sensitivity and specificity of 82.2% and 50.9% - both respectively. Based on receiver operator characteristic (ROC) curves, the ability of actigraphic measures to correctly classify a child as having an AHI of greater than one event/hour was considered to be poor.

Another study examined the validity of actigraphy for determining sleep and wake in children with sleep disordered breathing with data analyzed over four separate activity threshold settings (low, medium, high, auto).[22] The low and auto activity thresholds were found to adequately determine sleep (relative to PSG), but significantly underestimated wake, with sensitivity of 97% and specificity of 39%. The medium and high activity thresholds significantly underestimated sleep time, but were not found to be significantly different from the total PSG estimates of wake time. Overall agreement rates between actigraphy and PSG (for both sleep and wake) were 85% to 89%.

Discrepancy between actigraphic and sleep diary measures of sleep in adolescents was reported by Short in 2012.[23] A total of 290 adolescents (13 to 18 years) completed 8 days of sleep diaries and actigraphy. Actigraphic estimates of total sleep time (median of 6 hours 57 minutes) were significantly less than total sleep time recorded in adolescent's sleep diaries (median of 8 hours 17 minutes) or parent reports (median of 8 hours 51 minutes). Wake after sleep onset averaged 7 minutes in sleep diaries and 74 minutes by actigraphy. Actigraphy estimated wake after sleep onset of up to 3 hours per night in the absence of any wakening from sleep diaries, suggesting an overestimation of wake in this population. The discrepancy between actigraphy and sleep diary estimates of sleep was greater for boys than for girls, consistent with PSG studies showing increased nocturnal motor behavior in boys.

A validation study of actigraphy for determining sleep and wake was conducted in 10 preterm infants using videotaped behavioral observations.[24] The study was conducted for a 24-hour period each week while the infants were in the nursery, resulting in a total of 38 studies. Wakefulness was scored as quiet wake with eyes open and “bright”, active wake with eyes open and gross body movements, or crying. Sleep included quiet sleep with regular breathing and eyes closed, active sleep with irregular breathing and rapid eye movements, and indeterminant sleep, during which characteristics of both active and quiet sleep were observed. Behavioral sleep-wake scoring was carried out blinded to the knowledge of the actigraphy data. The actigraph, which was synchronized to the video recording, was placed in a custom-designed sleeve bandage and positioned on the infant’s leg midway between the knee and ankle. The agreement rate between actigraphic determination of sleep and wake, and behavioral scoring ranged from 66% for the high sensitivity setting at the youngest gestational age (30–33 weeks) to 89% at the low sensitivity setting for infants of 37–40 weeks’ gestational age. For the youngest infants, sensitivity and specificity at the low threshold were 88% and 34%, respectively. For infants of 37–40 weeks of gestational age, the sensitivity and specificity were 97% and 32%, respectively.

Similar results (97% sensitivity and 24% specificity) were obtained with an epoch-by-epoch comparison of actigraphy and videosomnography in 22 autistic, 11 developmentally delayed, and 25 normally developing preschool children.[25]

Insana (2010) compared ankle actigraphic recording and PSG in 22 healthy infants (13 to 15 months of age).[26] Actigraphy was found to underestimate total sleep time by 72 minutes and overestimate wake after sleep onset by 14 minutes. In 55% of the infants, total sleep time was underestimated by equal to or greater than 60 minutes. Sensitivity was calculated for total sleep time (92%), stages 1 and 2 combined (91%), slow wave sleep (96%), and REM sleep (89%). Specificity for identifying wake was 59%, and accuracy was 90%. Overall, actigraphy identified sleep relatively well but was unable to discriminate wake from sleep.

Another study compared wrist actigraphy with PSG in 149 healthy school-aged children.[27] Although the sleep period time was not significantly different, actigraphy was found to underestimate total sleep time by 32 minutes (correlation coefficient of 0.47) and overestimate wake after sleep onset by 26 minutes (correlation coefficient of 0.09). The authors concluded that actigraphy is relatively inaccurate for the determination of sleep quality in this population.

Additional studies[28-30] were identified which evaluated actigraphy in children; however, these studies were limited by small sample size precluding conclusions.

PRACTICE GUIDELINE SUMMARY

AMERICAN ACADEMY OF SLEEP MEDICINE (AASM) PRACTICE PARAMETERS

AASM Recommendation Classification

The recommendations of the American Academy of Sleep Medicine are categorized as follows, based on the level of evidence:[31]

- Standards describe a generally accepted patient care strategy, which reflects a high degree of clinical certainty based on Level 1 evidence or overwhelming Level 2 evidence.

- Guidelines reflect a moderate degree of clinical certainty from Level 2 evidence or a consensus of Level 3 evidence.
- Options reflect uncertain clinical use due to either inconclusive or conflicting evidence or conflicting expert opinion.

Translated into an evidence-based policy, indications classified as guidelines and options would be considered investigational due to the lower level of evidence.

The most recent update of the AASM Practice Parameters for the use of actigraphy in the assessment of sleep and sleep disorders[32] and circadian rhythm sleep disorders[31] was in 2007. Recommendations are summarized below.

Sleep and Sleep Disorders (other than circadian rhythm sleep disorders)[32]

Whereas the 2005[33] AASM guideline focused on the comparison of actigraphy with polysomnographically recorded sleep, the 2007 update included 108 additional studies comparing actigraphy to a number of standard clinical assessment tools including sleep logs, subjective questionnaires, care giver reports, and circadian phase markers. Recommendations are as follows:

Standards

Actigraphy was recommended as a "standard" only for the following:

1. To assist in determining sleep patterns in normal, healthy adult populations
2. As a method to estimate total sleep time in patients with obstructive sleep apnea syndrome when polysomnography is not available

Guidelines and Options

Other indications changed from "option" to "guidelines", but failed to reach a recommendation of "standard" due primarily to the absence of high-quality trials. Few of the studies reviewed had provided technical details related to the administration and scoring of actigraphy. In addition, most of the studies lacked a description of blinding, and there was "an inadequate description of whether visual inspection of data is performed, how missing data is handled, and other important decisions made in the analysis of actigraphy data." The options and guidelines are as follows:

1. To assist in the evaluation of patients suspected of the following:
    - advanced sleep phase syndrome (ASPS) (Guideline)
    - delayed sleep phase syndrome (DSPS) (Guideline)
    - shift work sleep disorder (Guideline)
2. For characterizing and monitoring sleep and circadian rhythm patterns and to document treatment outcome (in terms of sleep patterns and circadian rhythms) for the following:
    - older adults living in the community, particularly when used in conjunction with other measures such as sleep diaries and/or caregiver observations. (Guideline)
    - older nursing home residents (in whom traditional sleep monitoring by polysomnography can be difficult to perform and/or interpret). (Guideline)
3. For delineating sleep patterns, and to document treatment responses in normal infants and children (in whom traditional sleep monitoring by polysomnography can be difficult to perform and/or interpret), and in special pediatric populations. (Guideline)

Circadian Rhythm Sleep Disorders (CRSDs)[31,34]

In AASM's 2007 and 2008 Practice Parameter on evaluation and treatment of circadian rhythm sleep disorders (CRSDs), the use of actigraphy was considered as either an option or guideline, depending on the suspected disorder. The evidence reviewed indicated good agreement between actigraphy and results of other diagnostic tools including polysomnography, sleep logs, and markers of circadian phase. It should be noted, however, that there is a relative lack of evidence for any procedure in the diagnosis or evaluation of treatment of CRSDs. For example, use of sleep logs received a guideline recommendation, based primarily on consensus and inclusion in the second edition of the International Classification of Sleep Disorders (ICSD-2). Insufficient evidence was found to recommend use of circadian phase markers for any CRSDs other than free-running disorder. Polysomnography is not routinely indicated for the diagnosis of CRSDs. The options and guidelines are as follows:

1. To assist in the evaluation of patients suspected of circadian rhythm sleep disorders (CRSD) including the following:
    - jet lag (Option)
    - irregular sleep-wake disorder (ISWR) with or without blindness (Option)
    - free-running disorder (FRD) with or without blindness (Option)
    - It should be noted that there is a relative lack of evidence for any procedure in the diagnosis or evaluation of treatment of CRSDs
2. As a method to characterize circadian rhythm patterns or sleep disturbances in individuals with insomnia, including insomnia associated with depression. (Option)
3. As a way to determine circadian pattern and estimate average daily sleep time in individuals complaining of hypersomnia (Option).
4. As an outcome measure in evaluating the response to treatment for circadian rhythm disorders. (Guideline)

Recommendations for Future Research

The AASM Standards of Practice Committee indicated the need for additional research in the following areas:

- Comparison of results from different actigraphy devices and the variety of algorithms used
- Standards for setting start and stop times
- Reliability and validity compared to reference standards
- Clarification of the relative and unique contributions of actigraphy, polysomnography and sleep logs in the diagnosis of sleep disorders and measurement of treatment effects.
- Use of actigraphy in hypersomnia, especially as an adjunct to the Multiple Sleep Latency Test

SUMMARY

There is not enough research to show that actigraphy is as beneficial as the established alternatives in either adult or adolescent patients. Therefore, actigraphy is considered investigational.

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CODES

Codes	Number	Description
CPT	95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)
HCPCS	None	

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