Policy Replaced by LCD L36745 Effective October 1, 2016

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Actigraphy

Policy #: 164
Category: DME

Latest Review Date: February 2015
Policy Grade: B

Background:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Description of Procedure or Service:

Actigraphy refers to the assessment of activity patterns by devices typically placed on the wrist or ankle that record body movement, which is interpreted by computer algorithms as periods of sleep and wake. 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 might also be used to measure the level of physical activity.

Actigraphic devices are typically placed on the non-dominant wrist with a wristband and are worn continuously for at least 24 hours. Activity is usually recorded for a period of three days to two weeks, but can be collected continuously over extended time periods with regular downloading of data onto a computer. The activity monitors may also be placed on the ankle for the assessment of restless legs syndrome, or on the trunk to record movement in infants. 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. Sensitivity settings (e.g., low, medium, high, automatic) can also be adjusted during data analysis. 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 usually entered into the computer 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. Actigraph has been used for over two decades as an outcome measure in sleep disorders research.

Numerous actigraphy devices have received U.S. Food and Drug Administration (FDA) approval through the 510(k) process, with the first becoming available in 1987. Actigraphy devices designed and marketed to measure physical activity might also be used to measure sleep.

Policy:

Effective for dates of service on or after July 1, 2005:

Blue Advantage will treat **Actigraphy** to record and analyze body movement, including but not limited to its use to evaluate sleep disorders as a **non-covered** benefit and is considered **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies.

Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

This policy includes literature reviewed through January, 2015.

Assessment of a diagnostic technology typically focuses on three categories of evidence:

> Technical performance: Technical performance refers to how well the technology measures and records the parameter(s) that it is purported to evaluate. Evaluation of technical performance may include various measures of validity (e.g., criterion validity, construct validity, etc) and reliability (e.g. test-retest reliability, agreement among multiple reviewers, etc.).
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> Diagnostic accuracy: Diagnostic accuracy is the ability of a test to accurately diagnose a clinical condition in relevant populations of patients, in comparison to a reference standard. Measures of diagnostic accuracy include sensitivity, specificity, predictive values, likelihood ratios, and area under the curve analysis.
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> Impact on health outcomes: Demonstration that the diagnostic information can be used to improve patient outcomes is essential to determining the utility of a diagnostic technology. Direct evidence on the impact of the diagnostic technology on health outcomes may be available if controlled trials have been performed. In most cases, an indirect chain of evidence needs to be constructed to determine whether there is a tight linkage between the diagnostic technology and improvement in health outcomes.

This policy was initially based primarily on 2003 practice parameters issued by the American Academy of Sleep Medicine (AASM). Since all the specific clinical indications for actigraphy were classified as guidelines or options, the AASM practice parameters indicated that all indications for actigraphy would be considered investigational. In a review paper that served as the basis for the 2003 practice parameters, AASM pointed out the challenges in evaluating the diagnostic performance of actigraphy:

- Different actigraphy devices use different algorithms for the evaluation of data. There were no published articles comparing the different algorithms, making comparison between studies difficult.
- Polysomnography (PSG) is considered the criterion standard for the evaluation of sleep/wake cycles. However, correlation data may be misleading. For example, a high correlation on total sleep time would mean that individuals who slept longer by PSG criteria also slept longer by actigraphy criteria; however, this would not exclude the possibility that actigraphy data overestimated total sleep time. Different methods of analysis have also been used, such as accuracy for identification of true sleep and true

wake epochs. The diagnostic performance will also vary according to how much time the patient is asleep. For example, malfunctioning records will falsely identify the patient as asleep. Finally, comparisons between PSG and actigraphy have to be time-locked; if the two technologies gradually drift apart, different time epochs may be compared with each other.

- Published reports of actigraphy must contain complete reporting of sensitivity, specificity, scoring algorithm, and filters, as well as reliability, validity, ruggedness, and artifact rejection for the device and computer program used.

The 2005 Update for the AASM Practice Parameters continued to list actigraphy as an option and suggested areas such as restless legs syndrome and characterized circadian rhythm patterns for further evaluation. No controlled studies had been conducted to compare the results of actigraphy with other methods to determine if actigraphy would provide incremental information that would result in improved health outcomes.

In 2007, the AASM published updated practice parameters on the use of actigraphy in the assessment of sleep and sleep disorders. Whereas the 2005 practice parameters focused on the comparison of actigraphy with polysomnographically recorded sleep, the 2007 update included 108 additional studies comparing actigraphy with a number of standard clinical assessment tools that included sleep logs, subjective questionnaires, caregiver reports, and circadian phase markers. Actigraphy was recommended as a "standard" only as a method to estimate total sleep time in patients with obstructive sleep apnea syndrome when PSG is not available. Other indications changed from "option" to "guideline" 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 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 disorder and measurement of treatment effects

In AASM's 2007 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. Specifically, use of actigraphy was recommended as an option for diagnosis of irregular sleep-wake disorder and free-running disorder and as a guideline for diagnosis of advanced sleep phase disorder, delayed sleep phase disorder, and shift work 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.

Adults

Actigraphy Compared With PSG

Paquet et al (2007) compared actigraphic assessment of sleep and wake with PSB under varying conditions of sleep disturbance (night time sleep, daytime sleep, and daytime sleep with caffeine) in 23 healthy subjects. 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 one-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 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 actigraph 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.

Marino et al (2013) assessed clinical validity of wrist actigraphy to measure nighttime sleep using the Cole-Kripke algorithm in 54 young and older adults, either healthy or with insomnia, and in 23 night-workers during daytime sleep. Epoch by epoch comparison with PSG showed 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. As the amount of wake after sleep onset increased, the more that actigraphy underestimated this parameter. Several studies assessed clinical validity in patients with primary or secondary sleep disorders. One study by Sivertsen et al assessed the sensitivity and specificity of actigraphy in comparison with PSG in older adults treated for chronic primary insomnia. 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 36% of the time (specificity). The authors concluded that, “the clinical utility of actigraphy is still suboptimal in older adults treated for chronic primary insomnia.”

Kaplan et al (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. Blinded evaluation found no significant difference in sleep parameters between patients

with bipolar disorder and controls. Sleep parameter estimates from actigraphy and polysomnography were highly correlated.

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

Louter et al (2014) reported a study of actigraphy as a diagnostic aid for REM sleep behavior disorder (RBD) in 45 consecutive patients with Parkinson disease. The study population included patients referred for a variety of reasons, including insomnia, restless legs syndrome, and sleep apnea. Following video PSG, 23 patients were diagnosed with RBD. There was no significant difference between the two groups for the presence of other sleep disorders. Using a cutoff of 95 wake bouts per night, actigraphy had a sensitivity of 26.1% and specificity of 95.5%, with a positive predictive value of 85.7%.

Beecroft et al (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. 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 two to three 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. Similar findings were reported by van der Kooi et al in a study of seven short-term intensive-care unit patients; the median specificity was less than 19% when compared with PSG-recorded sleep. 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. 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. 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.

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. 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.

Actigraphy Compared With Sleep Diaries
Levenson et al (2013) evaluated the utility of sleep diaries and actigraphy to differentiate older adults with insomnia (n=79) from good sleeper controls (n=40). 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).

Children and Adolescents
Actigraphy Compared With PSG
In 2011, O'Driscoll et al reported a comparison of actigraphy with PSG in 130 children who had been referred for assessment of sleep-disordered breathing. The arousal index and apnea-hypopnea index (AHI) scored from PSG were compared with the number of wake bouts/hour and actigraphic fragmentation index. Using a PSG-determined AHI of greater than one 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 receiving operating characteristic curves, the ability of actigraphic measures to correctly classify a child as having an AHI of greater than one event/hour was considered poor.

Another 2007 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). 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 (sensitivity of 94% and 90%, respectively) but were not found to be significantly different from the total PSG estimates of wake time (specificity of 59% and 69%). Overall agreement rates between actigraphy and PSG (for both sleep and wake) were 85% to 89%. Sensitivity and specificity of different scoring algorithms were also assessed in healthy preschoolers. An algorithm designed specifically for children showed the highest accuracy (95.6%) in epoch-by-epoch comparison with PSG.

Insana et al (2010) compared ankle actigraphic recording and PSG in 22 healthy infants (13 to 15 months of age). 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. 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.

Actigraphy Compared With Sleep Diaries

Werner et al (2008) assessed agreement between actigraphy and parent diary or questionnaire for sleep patterns in 50 children, aged four to seven years, recruited from kindergarten schools in Switzerland. Sixty-eight families agreed to participate of 660 families invited (10%). Each child was home-monitored with an actigraph for six to eight 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. Parents' 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 study 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 were self-selected in this study.

Discrepancy between actigraphic and sleep diary measures of sleep in adolescents was reported by Short et al in 2012. A total of 290 adolescents (13 to 18 years) completed eight 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 seven minutes in sleep diaries and 74 minutes by actigraphy. Actigraphy estimated wake after sleep onset of up to three 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.

Actigraphy Compared With Behavioral Observations

A validation study of actigraphy for determining sleep and wake was conducted in ten preterm infants using videotaped behavioral observations. 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 REMs, and indeterminate 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 to 33 weeks) to 89% at the low sensitivity setting for infants of 37 to 40 weeks' gestational age. For the youngest infants, sensitivity and specificity at the low threshold were 88% and 34%, respectively. For infants of 37 to 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.

Actigraphy Compared With Video-electroencephalography (vEEG)
A prospective validation study of actigraphy for determining sleep-wake patterns in children with epilepsy was reported in 2014. In this study, 27 children with medically refractory epilepsy wore activity monitors while being evaluated with at least 24-hour vEEG (mean of 70.5 hours) in an inpatient epilepsy monitoring unit. vEEG and actigraphy data were evaluated by two independent and blinded reviewers. Although sensitivity and specificity were not reported, correlation coefficients between the two measures were very high (r=0.93 to 0.99) for night sleep period, night sleep time, duration of night wake time, and percent time of sleep during the day. Consistent with lower specificity to detect awakenings during sleep, the correlation for the number of awakenings after sleep onset was less robust.

Summary
The clinical validity of actigraphy, the assessment of activity patterns by devices typically placed on the wrist or ankle that record body movement, depends, to a large extent, on the modality with which it is being compared.

- Comparisons with sleep diaries show reasonable correlations for measure 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 quiet wake and sleep. The literature also indicates that the accuracy of actigraphy to differentiate between sleep and wake decreases as the level of sleep disturbance increases.

Overall, progress has been made since the 2007 AASM research recommendations in assessing the reliability and validity of different algorithms in comparison with the reference standard. Although actigraphy appears to provide reliable measures of sleep onset and wake time in some patient populations, the clinical utility of actigraphy over the less expensive sleep diary has not been demonstrated. Moreover, accumulating evidence indicates that actigraphy does not provide a reliable measure of sleep efficiency in clinical populations. Evidence to date does not indicate that this technology is as beneficial as the established alternative. Therefore, actigraphy is considered investigational.

Practice Guidelines and Position Statements

American Academy of Sleep Medicine Practice Parameters

The recommendations of the AASM are categorized as standards, guidelines, or options. Standards describe a generally accepted patient care strategy, which reflects a high degree of clinical certainty. Guidelines reflect a moderate degree of clinical certainty, while options imply either inconclusive or conflicting evidence or conflicting expert opinion. As noted here, there is only one recommendation considered a standard, and this addresses the technical performance of actigraphic devices (first bullet next paragraph). There is also only one recommended guideline (second bullet next paragraph), and this addresses the small subset of patients with insomnia and restless legs syndrome with specific indications. All of the other recommendations are considered options.

Recommendations of the AASM from 2003:

- Actigraphy is reliable and valid for detecting sleep in normal, healthy adult populations. (Standard)
- Actigraphy is not indicated for the routine diagnosis, assessment of severity, or management of any of the sleep disorders. However, it may be useful in the assessment of specific aspects of insomnia (assessment of sleep variability, measurement of treatment effects, detection of sleep phase alterations), and restless legs syndrome/periodic limb movement (assessment of treatment effects). (Guideline)
- Actigraphy may be a useful adjunct to a detailed history, examination, and subjective sleep diary for the diagnosis and treatment of insomnia, circadian-rhythm disorders, and excessive sleepiness under certain conditions. (Option)
- The use of actigraphy may be useful in assessing daytime sleepiness in situations where a more standard technique, such as a multiple sleep latency test, is not practical. (Option)
- Actigraphy is an effective means of demonstrating multiday human rest-activity pattern in clinical situations in which a sleep log, observations, or other methods cannot provide similar information. (Option)
- Actigraphy may be useful in characterizing and monitoring circadian rhythm patterns or disturbances in elderly and nursing home patients, newborns, infants, children, and adolescents; hypertensive individuals; depressed or schizophrenic patients; and individuals in inaccessible situations (i.e., space flight). (Option)
- Actigraphy appears useful as an outcome measure in interventional trials in patients with sleep disorders, outcome studies of healthy adults, patients with certain medical and psychiatric conditions, and children and the elderly. (Option)
- Actigraphy may be useful in determining the rest-activity pattern during portable sleep apnea testing. However, the use of actigraphy alone in the detection of obstructive sleep apnea is not currently established. (Option)
- Actigraphic studies should be conducted for a minimum of three consecutive 24-hour periods, but this length of time is highly dependent on the specific use in a given individual. (Option)

A 2005 Update for the AASM practice parameters continued to list actigraphy as an option and also suggested areas, such as restless legs syndrome and characterizing circadian rhythm patterns, for further evaluation.

Updated practice parameters in 2007 on the use of actigraphy in the assessment of sleep and sleep disorders (including a separate practice parameter on circadian rhythm sleep disorders) recommended actigraphy as a "standard" only as a method to estimate total sleep time in patients with obstructive sleep apnea syndrome when PSG is not available. Other indications changed from option to guideline, but failed to reach a recommendation of standard due primarily to the absence of high-quality trials.

AASM practice parameters from 2008 on clinical management of chronic insomnia in adults reference the 2007 practice parameters on actigraphy, stating 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.

Key Words:

Wrist actigraphic home monitoring, actigraphy, wrist-activity recording, wrist-activity monitoring, wrist mounted movement detector, ankle actigraphy monitoring

Approved by Governing Bodies:

Numerous actigraphy devices have received U.S. Food and Drug Administration (FDA) clearance for marketing 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.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

Current Coding:

CPT Codes:

	95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording) **(Effective January 1, 2009)**
HCPCS Code:	**E1399**	Durable medical equipment, miscellaneous **(Effective January 1, 2009)**

Previous Codes:

Effective for dates of service on or after July 1, 2005:

0089T	Actigraphy Testing, Recording, analysis and interpretation (Minimum of three-day recording) **(Code deleted effective January 1, 2009)**

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