



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Actigraphy

Policy # 00330

Original Effective Date: 07/27/2012

Current Effective Date: 07/20/2016

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Diagnosis and Management of Obstructive Sleep Apnea Syndrome is addressed separately in medical policy 00328.

Note: Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome is addressed separately in medical policy 00329.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers actigraphy when used as the sole technique to record and analyze body movement, including but not limited to its use to evaluate sleep disorders to be **investigational**.^{*} This does not include the use of actigraphy as a component of portable sleep monitoring.

Background/Overview

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 (absence of activity) and wake (activity). Actigraphic devices are typically placed on the nondominant wrist with a wristband and are worn continuously for at least 24 hours. Activity is usually recorded for a period of 3 days to 2 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" (the number of times per epoch that activity level crosses zero), or "digital integration" method, resulting in different sensitivities. Sensitivity settings (eg, 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. Actigraphy might also be used to measure the level of physical activity.

Actigraphy has been used for more than 2 decades as an outcome measure in sleep disorders research. For clinical applications, actigraphy is being evaluated as a measure of sleep/wake cycles in sleep



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Actigraphy

Policy # 00330

Original Effective Date: 07/27/2012

Current Effective Date: 07/20/2016

disorders including insomnia and circadian rhythm sleep disorders. In addition, actigraphy is being investigated as a measure of sleep/wake disturbances associated with numerous other diseases and disorders.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Numerous actigraphy devices have received U.S. 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.

FDA product code: OLV.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination.

Rationale/Source

Assessment of a diagnostic technology typically focuses on 3 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 (eg, criterion validity, construct validity, etc) and reliability (eg test-retest reliability, agreement among multiple reviewers, etc.).
- 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.
- 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). Because 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 accuracy 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

©2016 Blue Cross and Blue Shield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Actigraphy

Policy # 00330

Original Effective Date: 07/27/2012

Current Effective Date: 07/20/2016

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 2 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, 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 with 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

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



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Actigraphy

Policy # 00330

Original Effective Date: 07/27/2012

Current Effective Date: 07/20/2016

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.

Literature Review

Actigraphy is frequently used as an intermediate outcome in research studies. However, literature review updates have not identified any studies that evaluated whether the use of actigraphy would result in improved health outcomes for patients with sleep disorders. A number of studies have assessed sensitivity and specificity in either healthy or clinical populations (diagnostic accuracy). Following is a summary of key studies to date.

Adults

Actigraphy Compared With PSG

Paquet et al (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. Data were analyzed from a study that evaluated the effects of caffeine on daytime recovery sleep. The experimental protocol involved 2 visits to the sleep laboratory, each including 1 night of nocturnal sleep, 1 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 before 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% to 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 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 other studies assessed clinical validity in patients with primary or secondary sleep disorders. A 2006 study 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



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Actigraphy

Policy # 00330

Original Effective Date: 07/27/2012

Current Effective Date: 07/20/2016

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 study 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 8 nights of concurrent actigraphy and PSG. Sleep efficiency (actual sleep as a percentage of total recording time) 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 reported a study of actigraphy as a diagnostic aid for rapid eye movement (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 2 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 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 to 3 hours greater than PSG. Median sleep efficiency was estimated at 61% to 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 (2013) in a study of 7 short-term intensive care unit patients; median specificity was less than 19% when compared with PSG-recorded sleep. In a 2010 study, 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 3 collection modes (proportional integration, time above threshold, 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



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Actigraphy

Policy # 00330

Original Effective Date: 07/27/2012

Current Effective Date: 07/20/2016

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 (eg, foot or ankle), thresholds to define clinically significant PLMS (eg, 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; patients with insomnia completed PSG studies, but controls did not. Using receiver operating characteristic curve analysis, sleep diary measurements produced areas under the curve in the high range (0.84-0.97), whereas actigraphy performed less well at discriminating between older adults with insomnia and controls (areas under the curve, 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 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 10 events per hour as the reference standard, the actigraphic measure of wake bouts/hour had a sensitivity and a 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 operating characteristic curves, the ability of actigraphic measures to correctly classify a child as having an AHI of greater than 1 event/hour was considered poor.

A 2007 study examined the validity of actigraphy for determining sleep and wake in children with sleep disordered breathing with data analyzed over 4 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, 94% and 90%, respectively) but were not found to be significantly different from the total PSG estimates of wake time (specificity, 59% and 69%). Overall agreement rates between actigraphy and PSG (for both sleep and wake) were 85% to 89%. Belanger et al (2013) assessed sensitivity and specificity of different scoring algorithms in healthy preschoolers. An algorithm designed specifically for children showed the highest accuracy (95.6%) in epoch-by-epoch comparison with PSG.



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Actigraphy

Policy # 00330
Original Effective Date: 07/27/2012
Current Effective Date: 07/20/2016

Insana et al (2010) compared ankle actigraphic recording and PSG in 22 healthy infants (13-15 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 60 minutes or more. 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. A 2011 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, 0.47) and overestimate wake after sleep onset by 26 minutes (correlation coefficient, 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 4 to 7 years, recruited from kindergarten schools in Switzerland. Sixty-eight (10%) of 660 invited families agreed to participate. 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. 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 (13-18 years) completed 8 days of sleep diaries and actigraphy. Actigraphic estimates of total sleep time (median, 6 hours 57 minutes) were significantly less than total sleep time recorded in adolescent's sleep diaries (median, 8 hours 17 minutes) or parent reports (median, 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 waking 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 10 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



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Actigraphy

Policy # 00330

Original Effective Date: 07/27/2012

Current Effective Date: 07/20/2016

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 (30-33 weeks) to 89% at the low sensitivity setting for infants of 37 to 40 weeks of 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, sensitivity and specificity were 97% and 32%, respectively. Similar results (97% sensitivity and 24% specificity) were obtained in a 2008 study 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

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 video-electroencephalography (vEEG; mean, 70.5 hours) in an inpatient epilepsy monitoring unit. vEEG and actigraphy data were evaluated by 2 independent and blinded reviewers. Although sensitivity and specificity were not reported, correlation coefficients between the 2 measures were very high (r range, 0.93-0.99) 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 of Evidence

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 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 remain to be demonstrated.
- Comparisons with the more resource-intensive polysomnography 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.

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, evidence indicates that actigraphy does not provide a reliable measure of sleep efficiency in clinical populations.

©2016 Blue Cross and Blue Shield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Actigraphy

Policy # 00330

Original Effective Date: 07/27/2012

Current Effective Date: 07/20/2016

Evidence to date does not indicate that this technology is as beneficial as the established alternatives. Therefore, actigraphy is considered investigational.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Actigraphy", 2.01.73, 2:2015.
2. Littner M, Kushida CA, Anderson WM, et al. Practice parameters for the role of actigraphy in the study of sleep and circadian rhythms: an update for 2002. *Sleep*. May 1 2003;26(3):337-341. PMID 12749556
3. Ancoli-Israel S, Cole R, Alessi C, et al. The role of actigraphy in the study of sleep and circadian rhythms. *Sleep*. May 1 2003;26(3):342-392. PMID 12749557
4. Kushida CA, Littner MR, Morgenthaler T, et al. Practice parameters for the indications for polysomnography and related procedures: an update for 2005. *Sleep*. Apr 2005;28(4):499-521. PMID 16171294
5. Morgenthaler T, Alessi C, Friedman L, et al. Practice parameters for the use of actigraphy in the assessment of sleep and sleep disorders: an update for 2007. *Sleep*. Apr 2007;30(4):519-529. PMID 17520797
6. Morgenthaler TI, Lee-Chiong T, Alessi C, et al. Practice parameters for the clinical evaluation and treatment of circadian rhythm sleep disorders. An American Academy of Sleep Medicine report. *Sleep*. Nov 2007;30(11):1445-1459. PMID 18041479
7. Paquet J, Kawinska A, Carrier J. Wake detection capacity of actigraphy during sleep. *Sleep*. Oct 2007;30(10):1362-1369. PMID 17969470
8. Marino M, Li Y, Rueschman MN, et al. Measuring sleep: accuracy, sensitivity, and specificity of wrist actigraphy compared to polysomnography. *Sleep*. Nov 2013;36(11):1747-1755. PMID 24179309
9. Sivertsen B, Omvik S, Havik OE, et al. A comparison of actigraphy and polysomnography in older adults treated for chronic primary insomnia. *Sleep*. Oct 2006;29(10):1353-1358. PMID 17068990
Kaplan KA, Talbot LS, Gruber J, et al. Evaluating sleep in bipolar disorder: comparison between actigraphy, polysomnography, and sleep diary. *Bipolar Disord*. Dec 2012;14(8):870-879. PMID 23167935
10. Taibi DM, Landis CA, Vitiello MV. Concordance of polysomnographic and actigraphic measurement of sleep and wake in older women with insomnia. *J Clin Sleep Med*. Mar 15 2013;9(3):217-225. PMID 23493815
11. Louter M, Arends JB, Bloem BR, et al. Actigraphy as a diagnostic aid for REM sleep behavior disorder in Parkinson's disease. *BMC Neurol*. 2014;14:76. PMID 24708629
12. Beecroft JM, Ward M, Younes M, et al. Sleep monitoring in the intensive care unit: comparison of nurse assessment, actigraphy and polysomnography. *Intensive Care Med*. Nov 2008;34(11):2076-2083. PMID 18521566
13. van der Kooi AW, Tulen JH, van Eijk MM, et al. Sleep monitoring by actigraphy in short-stay ICU patients. *Crit Care Nurs Q*. Apr-Jun 2013;36(2):169-173. PMID 23470702
14. Dick R, Penzel T, Fietze I, et al. AASM standards of practice compliant validation of actigraphic sleep analysis from SOMNOwatch versus polysomnographic sleep diagnostics shows high conformity also among subjects with sleep disordered breathing. *Physiol Meas*. Dec 2010;31(12):1623-1633. PMID 21071830
15. Blackwell T, Ancoli-Israel S, Redline S, et al. Factors that may influence the classification of sleep-wake by wrist actigraphy: the MrOS Sleep Study. *J Clin Sleep Med*. Aug 15 2011;7(4):357-367. PMID 21897772
16. Plante DT. Leg actigraphy to quantify periodic limb movements of sleep: a systematic review and meta-analysis. *Sleep Med Rev*. Oct 2014;18(5):425-434. PMID 24726711
17. Levenson JC, Troxel WM, Begley A, et al. A quantitative approach to distinguishing older adults with insomnia from good sleeper controls. *J Clin Sleep Med*. Feb 1 2013;9(2):125-131. PMID 23372464
18. O'Driscoll DM, Foster AM, Davey MJ, et al. Can actigraphy measure sleep fragmentation in children? *Arch Dis Child*. Dec 2010;95(12):1031-1033. PMID 19850594
19. Hyde M, O'Driscoll DM, Binette S, et al. Validation of actigraphy for determining sleep and wake in children with sleep disordered breathing. *J Sleep Res*. Jun 2007;16(2):213-216. PMID 17542951
20. Belanger ME, Bernier A, Paquet J, et al. Validating actigraphy as a measure of sleep for preschool children. *J Clin Sleep Med*. Jul 15 2013;9(7):701-706. PMID 23853565
21. Insana SP, Gozal D, Montgomery-Downs HE. Invalidity of one actigraphy brand for identifying sleep and wake among infants. *Sleep Med*. Feb 2010;11(2):191-196. PMID 20083430
22. Spruyt K, Gozal D, Dayyat E, et al. Sleep assessments in healthy school-aged children using actigraphy: concordance with polysomnography. *J Sleep Res*. Mar 2011;20(1 Pt 2):223-232. PMID 20629939
23. Werner H, Molinari L, Guyer C, et al. Agreement rates between actigraphy, diary, and questionnaire for children's sleep patterns. *Arch Pediatr Adolesc Med*. Apr 2008;162(4):350-358. PMID 18391144

©2016 Blue Cross and Blue Shield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Actigraphy

Policy # 00330

Original Effective Date: 07/27/2012

Current Effective Date: 07/20/2016

24. Short MA, Gradisar M, Lack LC, et al. The discrepancy between actigraphic and sleep diary measures of sleep in adolescents. *Sleep Med.* Apr 2012;13(4):378-384. PMID 22437142
25. Sung M, Adamson TM, Horne RS. Validation of actigraphy for determining sleep and wake in preterm infants. *Acta Paediatr.* Jan 2009;98(1):52-57. PMID 18754828
26. Sitnick SL, Goodlin-Jones BL, Anders TF. The use of actigraphy to study sleep disorders in preschoolers: some concerns about detection of nighttime awakenings. *Sleep.* Mar 2008;31(3):395-401. PMID 18363316
27. Sadaka Y, Sadeh A, Bradbury L, et al. Validation of actigraphy with continuous video-electroencephalography in children with epilepsy. *Sleep Med.* Sep 2014;15(9):1075-1081. PMID 24974198
28. Schutte-Rodin S, Broch L, Buysse D, et al. Clinical guideline for the evaluation and management of chronic insomnia in adults. *J Clin Sleep Med.* Oct 15 2008;4(5):487-504. PMID 18853708

Policy History

Original Effective Date: 07/27/2012

Current Effective Date: 07/20/2016

- | | |
|-----------------------------|--|
| 06/28/2012 | Medical Policy Committee review |
| 07/27/2012 | Medical Policy Implementation Committee approval. New policy. |
| 06/27/2013 | Medical Policy Committee review |
| 07/17/2013 | Medical Policy Implementation Committee approval. No change to coverage. |
| 07/10/2014 | Medical Policy Committee review |
| 07/16/2014 | Medical Policy Implementation Committee approval. Investigational statement clarified regarding portable sleep monitoring. |
| 06/25/2015 | Medical Policy Committee review |
| 07/15/2015 | Medical Policy Implementation Committee approval. No change to coverage. |
| 06/30/2016 | Medical Policy Committee review |
| 07/20/2016 | Medical Policy Implementation Committee approval. No change to coverage. |
| 01/01/2017 | Coding update: Removing ICD-9 Diagnosis Codes |
| Next Scheduled Review Date: | 07/2017 |

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2015 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Actigraphy

Policy # 00330

Original Effective Date: 07/27/2012

Current Effective Date: 07/20/2016

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	95803
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.