Medical Policy

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Title: Actigraphy

Professional
Original Effective Date: January 1, 2009
Revision Date(s): October 19, 2009; May 20, 2011; June 5, 2012; June 7, 2013; July 10, 2015; November 15, 2017; August 15, 2018
Current Effective Date: July 10, 2015

Institutional
Original Effective Date: October 19, 2009
Revision Date(s): May 20, 2011; June 5, 2012; June 7, 2013; July 10, 2015; November 15, 2017; August 15, 2018
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Populations	Interventions	Comparators	Outcomes
Individuals: • With circadian sleep-wake rhythm disorders	Interventions of interest are: • Actigraphy	Comparators of interest are: • Polysomnography • Sleep journal	Relevant outcomes include: • Test accuracy • Test validity
Individuals: • With sleep–associated disorders in children and adolescents	Interventions of interest are: • Actigraphy	Comparators of interest are: • Polysomnography	Relevant outcomes include: • Test accuracy • Test validity
Individuals: • With central disorders of hypersomnolence	Interventions of interest are: • Actigraphy	Comparators of interest are: • Polysomnography • Sleep journal	Relevant outcomes include: • Test accuracy • Test validity
Individuals: • With insomnia	Interventions of interest are: • Actigraphy	Comparators of interest are: • Polysomnography • Sleep journal	Relevant outcomes include: • Test accuracy • Test validity

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DESCRIPTION

Actigraphy refers to the assessment of body movement activity patterns using devices, typically placed on the wrist or ankle during sleep, which are interpreted by computer algorithms as periods of sleep and wake. Sleep/wake cycles may be altered in sleep disorders, including insomnia and circadian rhythm sleep disorders. Also, actigraphy could be used to assess sleep/wake disturbances associated with other disorders.

Objective

The objective of this evidence review is to evaluate the situations in which actigraphy in the diagnosis of sleep disorders improves the net health outcome.

Background

SLEEP DISORDERS

Sleep disorders affect a large percentage of the U.S. population. For example, estimates suggest that 15% to 24% of the U.S. population suffers from insomnia.[1] Lack of sleep also contributes reduced cognitive functioning, susceptibility to heart disease, and workplace absenteeism.

Diagnosis

Actigraphy refers to the assessment of activity patterns (body movement) using devices, typically placed on the wrist or ankle, that are interpreted by computer algorithms as periods of sleep (absence of activity) and wake (activity). Actigraphy devices are usually 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 to assess restless legs syndrome or on the trunk to record movement in infants.

The algorithms for detecting movement vary across 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 most commonly used method (digital integration) reflects both acceleration and amplitude of movement.

Data on patient bed times (lights out) and rise times (lights on) are usually entered into the computer 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 the movement-related level of activity and periods of wake. In addition to providing graphic depiction of the activity pattern, the device-specific software can then analyze and report a variety of sleep parameters including sleep onset, sleep offset, sleep latency, total sleep duration, and wake after sleep onset (actigraphy could also be used to measure the level of physical activity).

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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 disorders including insomnia and circadian rhythm sleep disorders. Also, actigraphy is being investigated as a measure of sleep-wake disturbances associated with other diseases and disorders.

Regulatory Status

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

POLICY

Actigraphy is considered **experimental / investigational** when used as the sole technique to record and analyze body movement, including but not limited to its use to evaluate sleep disorders.

Policy Guidelines

This policy does not address the use of actigraphy when used as a component of portable sleep monitoring under CPT codes 95800 or 95806. When used as a component of portable sleep monitoring, actigraphy should not be separately reported.

RATIONALE

This evidence review has been updated with searches of the MEDLINE database. The most recent literature update was performed through April 30, 2018.

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

CIRCADIAN SLEEP-WAKE RHYTHM DISORDERS

Clinical Context and Test Purpose

The purpose of actigraphy monitoring in patients who have circadian sleep-wake rhythm disorders is to inform a decision regarding the etiology of abnormal sleep-wake patterns.

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The question addressed in this evidence review is: Does use of actigraphy in the diagnosis of sleep disorders improves the net health outcome?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is individuals with circadian sleep-wake rhythm disorders. The body's 24-hour internal physiologic systems, such as sleep, wakefulness, core temperature, and appetite are known as circadian rhythms. Disorders of circadian rhythms can be of the intrinsic system or precipitated by external factors (eg, shift work). Clinical manifestations may be insomnia or excessive daytime sleepiness.

Interventions

The test being considered is actigraphy.

Comparators

The following tests and tools are currently being used to make decisions about circadian sleep-wake rhythm disorders: polysomnography (PSG) and sleep diaries or logs. PSG is the criterion standard for the evaluation of sleep-wake cycles. A sleep diary is a key component of sleep disorders evaluation and includes the patient's record of symptoms.

Outcomes

Measurement of movement (actigraph) is typically 3 types: zero crossing mode counts the number of times the waveform crosses 0 for each time period; proportional integral mode measures the area under the curveand adds that size for each time period; and time above threshold uses a defined threshold and measures the length of time that the wave is above the threshold.

Timing

Actigraphy data is generally recorded for periods between 3 days to 2 weeks but can be collected continuously over extended periods with regular downloading of data onto a computer.

Setting

The setting of interest is an outpatient sleep laboratory or in the home.

Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review, and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Actigraphy vs Polysomnography

Paquet et al (2007) compared actigraphy assessment of sleep and wake with PSG under varying conditions of sleep disturbance (nighttime sleep, daytime sleep, daytime sleep with caffeine) in

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23 healthy subjects.[2] This study was ancillary to another 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 caffeine 200 mg). Actigraphy monitoring used a specific device applied to the wrist (Actiwatch), which was synchronized with PSG equipment before recording. Assessments of sleep and wake for each 1-minute interval were compared for sensitivity, specificity, and accuracy of actigraphy 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 sensitivity settings/scoring algorithms were compared. In general, as the threshold to detect movement increased, sensitivity to detect sleep increased, but the specificity to detect wake decreased. With the medium threshold algorithm, the sensitivity to detect sleep ranging between 95% and 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. The main study finding was that the more disturbed the sleep, the less actigraphy could 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 provided information on the limitations of this technology for clinical populations with sleep disruption.

No specific studies were identified that compared actigraphy with sleep diaries in clinical populations.

Section Summary: Clinical Validity

The diagnosis of circadian rhythm disorders in adults is made through a clinical evaluation that includes a review of sleep diaries or logs along with the use of PSG as necessary. Limited data indicates that the actigraphy is comparable to PSG for detecting sleep but less specific for detecting wake activity in disturbed sleep conditions. No specific studies were identified that compared actigraphy with sleep diaries in this patient population.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary testing or therapy.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

No direct evidence for the use of actigraphy in the management of circadian rhythm disorders was identified.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

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There were insufficient data on clinical validity to establish clinical utility.

Section Summary: Clinically Useful

There is a lack of evidence regarding whether actigraphy improves the net health outcome in individuals with circadian sleep-wake disorders.

CHILDREN OR ADOLESCENTS WITH SLEEP-RELATED DISORDERS

Clinical Context and Test Purpose

The purpose of actigraphy monitoring in children or adolescents with sleep-related disorders is to inform a decision whether the use of actigraphy in the diagnosis of sleep disorders improves the net health outcome.

Patients

The relevant population of interest is children or adolescents with sleep-related disorders. Maturation of the sleep-wake cycle is a developmental process from the newborn period through the pubertal period. Premature infants are prone to sleep disturbances. Sleep disorders may be considered in children and adolescents presenting with irritability, behavioral problems, learning difficulties, and poor academic performance.

Interventions

The test being considered is actigraphy.

Comparators

The following tests and tools are currently being used to make decisions about other sleeping disorders: PSG and sleep journal.

Outcomes

The general outcome of interest is accurate diagnosis of the sleep disorder leading to appropriate treatment and monitoring.

Timing

Actigraphy data is generally recorded for periods between 3 days to 2 weeks but can be collected continuously over extended periods with regular downloading of data onto a computer.

Setting

The setting of interest is an outpatient sleep laboratory or in the home.

Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review, and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid

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Actigraphy vs PSG

Randomized Controlled Trials

Meltzer et al (2016) compared actigraphy with concurrently worn comprehensive ambulatory home PSG among 148 children ages 5 to 12 born prematurely (see Table 1).[3] Subjects were participating in a larger study on the long-term effect of caffeine therapy for apnea of prematurity on sleep. After controlling for sleep disorders, compared with PSG, actigraphy underestimated total sleep by 30.1 minutes and overestimated sleep onset latency by 2.16 minutes (see Table 2). The sensitivity and specificity of actigraphy were 88% and 84%, respectively; accuracy was 46%.

Table 1. Summary of Key RCT Characteristics

Study	Countries	Sites	Participants	Interventions	
				Active	Comparator
Meltzer et al (2016)[3]	U.S., Australia	50	148 (85 male, 63 female) children born preterm	Caffeine	Placebo

RCT: randomized controlled trials.

Table 2. Summary of Key RCT Results

Study	Mean PSG (SD)	Mean Actigraphy (SD)	Mean Difference (95% CI)	p
Meltzer et al (2016)[3]				
Total sleep time, min	535.9 (54.8)	505.7 (49.3)	-30.1 (-35.3 to -25.0)	0.02
Sleep-onset latency, min	18.1 (18.8)	20.3 (23.0)	2.16 (-1.7 to 6.0)	0.02
Sleep efficiency, %	89.6 (0.05)	84.6 (0.05)	-5.0 (-5.8 to -4.1)	0.008

CI: confidence interval; PSG: polysomnography; RCT: randomized controlled trials; SD: standard deviation.

The purpose of the gaps tables (see Tables 3 and 4) is to display notable gaps identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.

Table 3. RCT Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Meltzer et al (2016)[3]	3. Study population is unclear 4. Study population not representative of intended use	3. Not intervention of interest			

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

[b] Intervention key: 1. Classification thresholds not defined; 2. Version used unclear; 3. Not intervention of interest.

[c] Comparator key: 1. Classification thresholds not defined; 2. Not compared to credible reference standard; 3. Not compared to other tests in use for same purpose.

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[d] Outcomes key: 1. Study does not directly assess a key health outcome; 2. Evidence chain or decision model not explicated; 3. Key clinical validity outcomes not reported (sensitivity, specificity and predictive values); 4. Reclassification of diagnostic or risk categories not reported; 5. Adverse events of the test not described (excluding minor discomforts and inconvenience of venipuncture or noninvasive tests).
[e] Follow-Up key: 1. Follow-up duration not sufficient with respect to natural history of disease (true positives, true negatives, false positives, false negatives cannot be determined).

Table 4. Study Design and Conduct Gaps

Study	Selection[a]	Blinding[b]	Delivery of Test[c]	Selective Reporting[d]	Data Completeness[e]	Statistical[f]
Meltzer et al (2016)[3]	3. Selection not described					

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Selection key: 1. Selection not described; 2. Selection not random or consecutive (ie, convenience).
[b] Blinding key: 1. Not blinded to results of reference or other comparator tests.
[c] Test Delivery key: 1. Timing of delivery of index or reference test not described; 2. Timing of index and comparator tests not same; 3. Procedure for interpreting tests not described; 4. Expertise of evaluators not described.
[d] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[e] Data Completeness key: 1. Inadequate description of indeterminate and missing samples; 2. High number of samples excluded; 3. High loss to follow-up or missing data.
[f] Statistical key: 1. Confidence intervals and/or p values not reported; 2. Comparison to other tests not reported.

Nonrandomized Trials

Trial characteristics and results are provided in Tables 5 and 6.

O'Driscoll et al (2010) compared actigraphy with PSG in 130 children referred for assessment of sleep-disordered breathing.[4] The Arousal Index and Apnea-Hypopnea Index scores from PSG were compared with the number of wake bouts per hour and Fragmentation Index. Using a PSG-determined Apnea-Hypopnea Index of greater than 1 event per hour, the measure of wake bouts per 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 actigraphy measure of wake bouts per 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 operating characteristic curves, the ability of actigraphy to classify child correctly as having an Apnea-Hypopnea Index of greater than 1 event per hour was considered poor.

Hyde et al (2007) examined the validity of actigraphy for determining sleep and wake in children with sleep-disordered breathing using data analyzed over 4 separate activity threshold settings (low, medium, high, automatic).[5] The low- and auto-activity thresholds were found to determine sleep adequately (relative to PSG) but to underestimate wake significantly, with a sensitivity of 97% and specificity of 39%. The medium- and high-activity thresholds significantly underestimated sleep time (sensitivity, 94% and 90%) but did not differ significantly from the total PSG estimates of wake time (specificity, 59% and 69%), respectively. Overall agreement rates between actigraphy and PSG (for both sleep and wake) ranged from 85% to 89%. Belanger et al (2013) assessed the sensitivity and specificity of different scoring algorithms in healthy preschoolers.[6] An algorithm designed specifically for children showed the highest accuracy (95.6%) in epoch-by-epoch comparison with PSG.

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Insana et al (2010) compared ankle actigraphy recording with PSG in 22 healthy infants (age range, 13-15 months).[7] Actigraphy underestimated total sleep time by 72 minutes and overestimated 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 rapid eye movement 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 study by Spruyt et al (2011) compared wrist actigraphy with PSG in 149 healthy school-aged children.[8] Although sleep time did not differ significantly, actigraphy underestimated total sleep time by 32 minutes (ρ=0.47) and overestimated wake after sleep onset by 26 minutes (ρ=0.09). The authors concluded that actigraphy was relatively inaccurate for determining sleep quality in this population.

Table 5. Summary of Key Nonrandomized Trial Characteristics

Study	Study Type	Country	Participants	Treatment	Comparator
O'Driscoll et al (2010)[4]	Cohort	Australia	130 children ages 2-18 y	Actigraphy	PSG
Hyde et al (2007)[5]	Cohort	Australia	45 children ages 1-12 y	Actigraphy	PSG
Belanger et al (2013)[6]	Cohort	Canada	12 children ages 2-5 y	Actigraphy algorithms	PSG
Insana et al (2010)[7]	Cohort	U.S.	22 infants (14.1 mo)	Actigraphy	PSG

PSG: polysomnography.

Table 6. Summary of Key Nonrandomized Trial Results

Study	Sen, %	Spec, %	Accuracy	Total Sleep Time min
O'Driscoll et al (2010)[4]	82.2	50.9	-	-
	Median (IQR), %	**Median (IQR), %**		**Median (IQR)**
Hyde et al (2007)[5]				
Low	96.5 (94.4-98.8)	39.4 (15.5-67.3)	NA	424 (397-453)
Median	93.9 (90.9-97.1)	59.0 (28.7-82.1)	NA	402 (376-433)
High	90.1 (85.3-94.6)	68.9 (40.6-92.6)	NA	388 (358-417)
Auto	97.7 (96.2-98.4)	39.4 (22.9-53.9)	NA	426 (404-459)
	Mean (SD)	**Mean (SD)**	**Mean (SD), %**	**Mean (SD)**
Belanger et al (2013)[6]				
ACT40	87.9 (2.7)	500.7 (48.2)	87.5 (2.8)	500.7 (48.2)
ACT80	93.4 (1.6)	537.3 (50.0)	91.4 (2.1)	537.3 (50.0)
AlgoSmooth	97.7 (1.6)	565.1 (54.0)	95.0 (2.2)	565.1 (54.0)
	Sens (Range), %	**Spec (Range), %**	**Accuracy (Range), %**	
Insana et al (2010)[7]				
Stages 1-2	91.24 (79.6-97.9)	NA	NA	NA
Slow wave sleep	96.3 (73.1-100)	NA	NA	NA
REM sleep	88.9 (75.4-97.9)	NA	NA	NA
Total sleep time	92.4 (79.4-97.7)	NA	NA	NA

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Wake	NA	58.9 (0-100)	NA	NA
Total sleep/total wake	NA	NA	89.6 (65.4-97.7)	NA

IQR: interquartile range: NA: not applicable; REM: rapid eye movement; Sens: sensitivity; Spec: specificity.

Actigraphy vs Sleep Diaries

Werner et al (2008) assessed the agreement between actigraphy and parent diary or questionnaire to assess sleep patterns in 50 children, ages 4 to 7 years, recruited from kindergarten schools in Switzerland.[9] Sixty-eight (10%) of 660 invited families participated. Each child was home-monitored with an actigraph for 6 to 8 consecutive nights, and parents were asked 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 was obtained through a questionnaire. The 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. There was a lack of concordance between actigraphy and the questionnaire for any outcome parameter. Authors concluded that the diary was a cost-effective and valid source of information about children's sleep-schedule time, while actigraphy might provide additional information about nocturnal wake time or might be used if parents are unable to report in detail. Compliance and accuracy in the diaries were likely affected by parents' motivation, who self-selected into this study.

Sleep discrepancies between actigraphy and sleep diary measures in adolescents were reported by Short et al (2012).[10] A total of 290 adolescents (age range, 13-18 years) completed 8 days of sleep diaries and actigraphy. Actigraphy estimates of total sleep time (median, 6 hours 57 minutes) were significantly lower 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 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 that have shown increased nocturnal motor behavior in boys.

Section Summary: Clinical Validity

A single ancillary study within an RCT compared actigraphy with concurrently worn comprehensive ambulatory home PSG in a group of children born prematurely. The sensitivity and specificity of actigraphy were 88% and 84%, respectively; accuracy was 46%. Nonrandomized comparator studies testing multiple actigraphy threshold algorithms demonstrated low specificity for differentiating sleep-wake patterns. A complication of trials in this population is that sleep diaries or parent observation logs may be difficult to obtain for comparison with actigraphy data.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

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Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

No direct evidence for the use of actigraphy in the management of sleep-related disorders in children and adolescents was identified.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

There were insufficient data on clinical validity to establish clinical utility.

Section Summary: Clinically Useful
There is a lack of evidence regarding whether actigraphy improves the net health outcome in children or adolescents with other sleeping disorders.

CENTRAL DISORDERS OF HYPERSOMNOLENCE
Clinical Context and Test Purpose
The purpose of actigraphy monitoring in patients who have central disorders of hypersomnolence is to inform a decision whether the use of actigraphy in the diagnosis of sleep disorders improves the net health outcome.

Patients
The relevant population of interest is individuals with central disorders of hypersomnolence. Hypersomnolence is excessive sleepiness when wakefulness would be expected. Such disorders include narcolepsy, recurrent hypersomnia (Kleine-Levin syndrome) and idiopathic hypersomnia. Central nervous system tumors and neurodegenerative conditions may also present with hypersomnolence.

Interventions
The test being considered is actigraphy.

Comparators
The following tests and tools are currently being used to make decisions about other sleeping disorders: PSG and sleep journals.

Outcomes
The general outcome of interest is accurate diagnosis of the sleep disorder leading to appropriate treatment and monitoring.

Timing
Actigraphy data is generally recorded for periods between 3 days to 2 weeks but can be collected continuously over extended periods with regular downloading of data onto a computer.

Setting
The setting of interest is an outpatient sleep laboratory or in the home.

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Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review, and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Louter et al (2014) reported on a study of actigraphy, compared with video-PSG, as a diagnostic aid for rapid eye movement sleep behavior disorder in 45 consecutive patients with Parkinson disease.[11] 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 rapid eye movement sleep behavior disorder. There was no significant difference between 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%.

Section Summary: Clinically Valid

A single study was identified, and it evaluated actigraphy in hypersomnolence of central origin. The complexity of the various syndromes as well as the potential for medical treatment with significant adverse events makes accurate diagnosis essential. PSG and related secondary studies are the standard testing for evaluation of hypersomnolence.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

No direct evidence for the use of actigraphy in the management of central hypersomnolence was identified.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

There were insufficient data on clinical validity to establish clinical utility.

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Section Summary: Clinical Utility

There is a lack of evidence assessing whether actigraphy improves the net health outcome in individuals with central disorders of hypersomnolence. The evidence is insufficient to determine the effects of the technology on health outcomes.

INSOMNIA

Clinical Context and Test Purpose

The purpose of actigraphy monitoring in patients who have insomnia is to inform a decision whether the use of actigraphy in the diagnosis of sleep disorders improves the net health outcome.

Patients

The relevant population of interest is individuals with insomnia. The inability to fall asleep at an appropriate or desired time and to maintain sleep without excessive waking has multiple medical as well as psychosocial etiologies.

Interventions

The test being considered is actigraphy.

Comparators

The following tests and tools are currently being used to make decisions about insomnia: PSG and sleep journal.

Outcomes

The general outcome of interest is accurate diagnosis of the sleep disorder leading to appropriate treatment and monitoring.

Timing

Actigraphy data is generally recorded for periods between 3 days to 2 weeks but can be collected continuously over extended periods with regular downloading of data onto a computer.

Setting

The setting of interest is an outpatient sleep laboratory or in the home.

Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review, and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Marino et al (2013) assessed the 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.[12] Epoch-by-epoch comparison with PSG showed sensitivity (ability to detect sleep, 97%) and accuracy (86%) during the usual sleep/lights-out

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period to be high, but specificity (ability to detect wake, 33%) was low. As the amount of wake after sleep onset time increased, the more actigraphy underestimated this parameter. Several other studies have assessed the clinical validity of patients with primary or secondary sleep disorders.

Sivertsen et al (2006) assessed the sensitivity and specificity of actigraphy and PSG in older adults treated for chronic primary insomnia.[13] Visual scoring of PSG data was blinded, and actigraphy records were scored by proprietary software. The study found that actigraphy had a 95% sensitivity for the 30-second epochs, but only a 36% specificity for detecting wake time. The authors concluded that “the clinical utility of actigraphy” was “suboptimal in older adults treated for chronic primary insomnia.” Kaplan et al (2012) compared outcomes for actigraphy, PSG, and sleep diaries in 27 patients with bipolar disorder, who were between mood episodes, and in 27 age- and sex-matched controls.[14] Blinded evaluation found no significant differences in sleep parameters between patients with bipolar disorder and controls. Sleep parameter estimates from actigraphy and PSG 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.[15] 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. Actigraphy 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.

Levenson et al (2013) evaluated the utility of sleep diaries and actigraphy in differentiating older adults with insomnia (n=79) from good sleeper controls (n=40).[16] 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 those with insomnia and controls (area under the curve range, 0.58-0.61).

Dick et al (2010) assessed actigraphy with a SOMNOwatch in 28 patients with sleep-disordered breathing and reported a sensitivity of 90%, a specificity of 95%, and overall accuracy of 86% compared with PSG.[17] Pearson 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).

Section Summary: Clinically Valid

Multiple nonrandomized comparator and observational studies were identified to assess the use of actigraphy in the evaluation of chronic insomnia. The heterogeneity of etiologies for the condition necessitates a combination of clinical evaluation, sleep diaries, other reports of patient symptomatology and activity, as well as formal sleep studies. Actigraphy accurately measured total sleep time but not other measures of sleep patterning (eg, sleep latency).

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Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

No direct evidence for the use of actigraphy in the management of chronic insomnia was identified.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

There were insufficient data on clinical validity to establish clinical utility.

Section Summary: Clinical Utility

There is a lack of evidence assessing whether actigraphy improves the net health outcome in individuals with chronic insomnia.

SUMMARY OF EVIDENCE

For individuals who have circadian sleep-wake rhythm disorders who receive actigraphy, the evidence includes an ancillary study within a randomized controlled trial. Relevant outcomes are test accuracy and test validity. Comparison with PSG has shown that actigraphy is limited in differentiating between sleep and wake in more disturbed sleep. Actigraphy appears to reliably measure sleep onset and total sleep time in some patient populations. Comparisons with PSG and sleep diaries are limited. Evidence has shown that actigraphy does not provide a reliable measure of sleep efficiency in this patient population. The evidence is insufficient to determine the effects of the technology on health outcomes.

For children and adolescents with sleep-associated disorders, in children and adolescents who receive actigraphy, the evidence includes prospective and retrospective validation studies. Relevant outcomes are test accuracy and validity. Comparisons with PSG have shown that actigraphy can differ significantly in its estimations of wake and sleep times and sleep onset latency. Comparisons with sleep diaries have also failed to show satisfactory agreement, with greater discrepancies for more disturbed sleep. Evidence has shown that actigraphy does not provide a reliable measure of sleep efficiency in this patient population. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have central disorders of hypersomnolence who receive actigraphy, the evidence includes a comparative observational study. Relevant outcomes are test accuracy and validity. Comparison with video-PSG has indicated that actigraphy has a sensitivity of 26.1% and specificity of 95.5%. General evidence has also revealed that the accuracy of actigraphy for differentiating between wake and sleep decreases as the level of sleep disturbance increases. Although actigraphy appears to provide reliable measures of sleep onset and wake time in some

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patient populations, its clinical utility compared with that of sleep diaries has not been demonstrated. Evidence has shown that actigraphy does not provide a reliable measure of sleep efficiency in this patient population. The complexity of the various syndromes as well as the potential for medical treatment with significant adverse events makes accurate diagnosis essential. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have insomnia who receive actigraphy, the evidence includes prospective and retrospective validation studies. Relevant outcomes are test accuracy and validity. Comparisons with PSG have shown that actigraphy has poor agreement for reporting wake time and can overestimate sleep efficiency. Comparison with sleep diaries has indicated that actigraphy is less effective at differentiating between patients with insomnia and controls. General evidence has also revealed that the accuracy of actigraphy for differentiating between wake and sleep decreases as the level of sleep disturbance increases. Although actigraphy appears to provide reliable measures of sleep onset and wake time in some patient populations, its clinical utility compared with sleep diaries has not been demonstrated. Evidence has shown that actigraphy does not provide a reliable measure of sleep efficiency in this patient population. The evidence is insufficient to determine the effects of the technology on health outcomes.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Academy of Sleep Medicine

The American Academy of Sleep Medicine updated its 2007 practice parameters in 2015 on the use of actigraphy for the assessment of sleep and sleep disorders as well as circadian rhythm sleep disorders (see Table 7).[18-20]

Table 7. Recommendations for Actigraphy

Condition	Actigraphy for Diagnosis	Actigraphy to Measure Treatment Response
Shift work disorder	Indicated (option)	Indicated (guideline)
Jet lag disorder	Not routinely indicated (option)	Indicated (guideline)
Advanced sleep phase disorder	Indicated (guideline)	Indicated (guideline)
Delayed sleep phase disorder	Indicated (guideline)	Indicated (guideline)
Free-running disorder	Indicated (option)	Indicated (guideline)
Irregular sleep-wake rhythm	Indicated (option)	Indicated (guideline)

“Standards” describe a generally accepted patient care strategy, which reflects a high degree of clinical certainty. “Guidelines” reflect a moderate degree of clinical certainty. “Options” imply either inconclusive or conflicting evidence or conflicting expert opinion.

The American Academy of Sleep Medicine practice parameters from 2008 evaluated the clinical management of chronic insomnia in adults, 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.[21]

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

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CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

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

- There is a CPT category I code for this testing: 95803.

DIAGNOSIS

Experimental / investigational for all diagnoses related to this policy.

REVISIONS

10-19-2009	Policy added to bcbsks.com web site.
05-20-2011	Rationale updated
	References updated
06-05-2012	Rationale section updated
	References updated
06-07-2013	Description section updated
	Rationale section updated
	References updated
07-10-2015	Policy published on 06-10-2015 for an effective date of 07-10-2015.
	Description section updated
	In Policy section: ▪ Added "when used" and "the sole" to read, "Actigraphy is considered experimental / investigational when used as ~~a~~ the sole technique to record and analyze body movement, including but not limited to its use to evaluate sleep disorders."
	Rationale section updated
	In Coding section: ▪ Coding notations added.
	References updated
11-15-2017	Description section updated
	In Policy section: ▪ Policy Guidelines added
	Rationale section updated
	References updated
08-15-2018	Description section updated
	Rationale section updated
	References updated

REFERENCES

1. Ford ES, Cunningham TJ, Giles WH, et al. Trends in insomnia and excessive daytime sleepiness among U.S. adults from 2002 to 2012. Sleep Med. Mar 2015;16(3):372-378. PMID 25747141
2. Paquet J, Kawinska A, Carrier J. Wake detection capacity of actigraphy during sleep. Sleep. Oct 2007;30(10):1362-1369. PMID 17969470

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3. Meltzer LJ, Wong P, Biggs SN, et al. Validation of actigraphy in middle childhood. Sleep. Jun 01 2016;39(6):1219-1224. PMID 27091520
4. 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
5. 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
6. 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
7. 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
8. 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
9. 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
10. 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
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. Apr 06 2014;14:76. PMID 24708629
12. 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
13. 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
14. 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
15. 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
16. 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
17. 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
18. 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
19. 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
20. Auger RR, Burgess HJ, Emens JS, et al. Clinical Practice Guideline for the Treatment of Intrinsic Circadian Rhythm Sleep-Wake Disorders: Advanced Sleep-Wake Phase Disorder (ASWPD), Delayed Sleep-Wake Phase Disorder (DSWPD), Non-24-Hour Sleep-Wake Rhythm Disorder (N24SWD), and Irregular Sleep-Wake Rhythm Disorder (ISWRD). An Update for 2015: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. Oct 15 2015;11(10):1199-1236. PMID 26414986
21. 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

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