`PHP_2.01.73	Actigraphy		
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State Guidelines

As of the publication of this policy, there are no applicable Medi-Cal guidelines (Provider Manual or All Plan Letter). Please refer to the Policy Statement section below.

Policy Statement

In the absence of any State Guidelines, please refer to the criteria below.

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

This does not include the use of actigraphy as a component of portable sleep monitoring (see Policy Guidelines section).

Policy Guidelines

This policy does not address the use of actigraphy 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.

Coding

See the Codes table for details.

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.

Summary of Evidence

For individuals who have circadian sleep-wake rhythm disorders who receive actigraphy, the evidence includes a comparative study that selected subjects from another main study evaluating the effects of caffeine on daytime recovery sleep. Relevant outcomes are test accuracy and test validity. Comparison with polysomnography (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 that the technology results in an improvement in the net health outcome.

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For children and adolescents with sleep-associated disorders 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 that the technology results in an improvement in the net health outcome.

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 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 that the technology results in an improvement in the net health outcome.

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 a 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 that the technology results in an improvement in the net health outcome.

Additional Information
Not applicable.

Related Policies

- N/A

Benefit Application

Blue Shield of California Promise Health Plan is contracted with L.A. Care Health Plan for Los Angeles County and the Department of Health Care Services for San Diego County to provide Medi-Cal health benefits to its Medi-Cal recipients. In order to provide the best health care services and practices, Blue Shield of California Promise Health Plan has an extensive network of Medi-Cal primary care providers and specialists. Recognizing the rich diversity of its membership, our providers are given training and educational materials to assist in understanding the health needs of their patients as it could be affected by a member's cultural heritage.

The benefit designs associated with the Blue Shield of California Promise Medi-Cal plans are described in the Member Handbook (also called Evidence of Coverage).

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Regulatory Status

Numerous actigraphy devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) 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.

Health Equity Statement

Blue Shield of California Promise Health Plan's mission is to transform its health care delivery system into one that is worthy of families and friends. Blue Shield of California Promise Health Plan seeks to advance health equity in support of achieving Blue Shield of California Promise Health Plan's mission.

Blue Shield of California Promise Health Plan ensures all Covered Services are available and accessible to all members regardless of sex, race, color, religion, ancestry, national origin, ethnic group identification, age, mental disability, physical disability, medical condition, genetic information, marital status, gender, gender identity, or sexual orientation, or identification with any other persons or groups defined in Penal Code section 422.56, and that all Covered Services are provided in a culturally and linguistically appropriate manner.

Rationale

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 to 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, which 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 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 the "digital integration" method, resulting in different sensitivities. Sensitivity settings (e.g., 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 bedtimes (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 a 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.

Literature Review

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 is to provide a diagnostic option that is an alternative to or an improvement on existing tests in the assessment of individuals with circadian sleep-wake rhythm disorders.

The following PICO was used to select literature to inform this review.

Populations

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 (e.g., shift work). Clinical manifestations may be insomnia or excessive daytime sleepiness.

Interventions

The test being considered is actigraphy.

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. Actigraphy data are 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.

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. Polysomnography 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 individual's record of symptoms.

Outcomes

The general outcomes of interest are test validity and test accuracy. 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 curve (AUC) and 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.

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Study Selection Criteria

For the evaluation of clinical validity of actigraphy, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores);
- Included a suitable reference standard;
- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described.

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).

Review of Evidence

Actigraphy versus 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 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 ranged between 95% and 96%. However, specificity or the ability to detect wake, was 54% for nighttime 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.

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, 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 (RCTs).

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

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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.

Limited data indicated that actigraphy is comparable to PSG for detecting sleep, but is less specific for detecting wake activity in disturbed sleep conditions.

Section Summary: Circadian Sleep-Wake Rhythm Disorders
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. For individuals who have circadian sleep-wake rhythm disorders who receive actigraphy, 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.

Children or Adolescents with Sleep-Related Disorders
Clinical Context and Test Purpose
The purpose of actigraphy is to provide a diagnostic option that is an alternative to or an improvement on existing tests in the assessment of children and adolescents with sleep-associated disorders.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is children or adolescents with sleep 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.

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. Actigraphy data are 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.

Comparators
The following tests and tools are currently being used to make decisions about sleep-associated disorders in children and adolescents: PSG and sleep diaries or logs. Polysomnography 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 individual's record of symptoms.

Outcomes
The general outcomes of interest are test validity and test accuracy. 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 AUC and 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.

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Study Selection Criteria

For the evaluation of clinical validity of actigraphy, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores);
- Included a suitable reference standard;
- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described.

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).

Review of Evidence

Actigraphy versus Polysomnography

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 (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 (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 trial.

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)	.02
Sleep-onset latency, min	18.1 (18.8)	20.3 (23.0)	2.16 (-1.7 to 6.0)	.02
Sleep efficiency, %	89.6 (0.05)	84.6 (0.05)	-5.0 (-5.8 to -4.1)	.008

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

Tables 3 and 4 display notable limitations identified in each study.

Table 3. Study Relevance Limitations

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 study limitations 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.

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[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.
[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 Limitations

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 study limitations 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 (i.e., 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 with other tests not reported.

Nonrandomized Studies

Enomoto et al (2022) evaluated the validity of a waist-worn actigraph with algorithm compared to PSG in 65 healthy children (age, 6 to 15 years) to determine sleep and wakefulness.[4] Children wore actigraph and received PSG simultaneously. The mean agreement rate of the actigraphy to PSG was 91.0%, with a mean sensitivity (true sleep detection rate) of 93% and a mean specificity (true wakefulness detection rate) of 63.9%.

Yavuz-Kodat et al (2019) evaluated the validity of actigraphy compared to PSG in 26 children (6 girls; 20 boys) with autism spectrum disorder.[5] Per equivalence tests, the difference between actigraphy and PSG measures were clinically acceptable for total sleep time (<30 minutes; p<.01), sleep latency (<15 minutes; p<.001), and sleep efficiency (10%, p<.01), but not for wake after sleep onset (<15 minutes; p=.13). The study involved a sample size of only 26 subjects with high inter-individual variability, which may result in reduced statistical power. Additionally, the investigators only compared a single night of actigraphy to concurrent PSG readings versus the recommended collection of 5 to 7 nights of recordings.

O'Driscoll et al (2010) compared actigraphy with PSG in 130 children referred for assessment of sleep-disordered breathing.[6] 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%, respectively. Based on receiver operating characteristic (ROC) curves, the ability of actigraphy to classify a child correctly as having an Apnea-Hypopnea Index of greater than 1 event per hour was considered poor.

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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).[7] 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.[8] An algorithm designed specifically for children showed the highest accuracy (95.6%) in epoch-by-epoch comparison with PSG.

Insana et al (2010) compared ankle actigraphy recording with PSG in 22 healthy infants (age range, 13 to 15 months).[9] 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.[10] Although sleep time did not differ significantly, actigraphy underestimated total sleep time by 32 minutes (p=.47) and overestimated wake after sleep onset by 26 minutes (p=.09). The authors concluded that actigraphy was relatively inaccurate for determining sleep quality in this population. Selected trial characteristics and results are provided in Tables 5 and 6.

Table 5. Summary of Key Nonrandomized Trial Characteristics

Study	Study Type	Country	Participants	Treatment	Comparator
Enomoto et al (2022)[4]	Cohort	Japan	65 children (ages, 6 to 15 y)	Actigraphy algorithm	PSG
Yavuz-Kodat et al (2019)[5]	Cohort	France	26 children (mean age: 5.4 y)	Actigraphy	PSG
O'Driscoll et al (2010)[6]	Cohort	Australia	130 children ages 2 to 18 y	Actigraphy	PSG
Hyde et al (2007)[7]	Cohort	Australia	45 children ages 1 to 12 y	Actigraphy	PSG
Belanger et al (2013)[8]	Cohort	Canada	12 children ages 2 to 5 y	Actigraphy algorithms	PSG
Insana et al (2010)[9]	Cohort	U.S.	22 infants (mean age: 14.1 mo)	Actigraphy	PSG

PSG: polysomnography.

Table 6. Summary of Key Nonrandomized Trial Results

Study	Sens, %	Spec, %	Accuracy	Total Sleep Time min
Enomoto et al (2022)[4]	92.95 ± 6.32	63.88 ± 35.82	91.04 ± 4.94%	385.97 ± 34.96
Yavuz-Kodat et al (2019)[5]*	Mean (SD)	Mean (SD)	Mean (SD)	
Low	0.94 ± 0.06	0.51 ± 0.20	0.87 ± 0.08	NA
Medium	0.90 ± 0.06	0.62 ± 0.19	0.86 ± 0.07	NA
High	0.86 ± 0.07	0.67 ± 0.18	0.83 ± 0.07	NA
Auto	0.94 ± 0.05	0.51 ± 0.15	0.86 ± 0.08	NA
O'Driscoll et al (2010)[6]	82.2	50.9	-	-
Hyde et al (2007)[7]	Median (IQR), %	Median (IQR), %		Median (IQR)
Low	96.5 (94.4 to 98.8)	39.4 (15.5 to 67.3)	NA	424 (397 to 453)
Median	93.9 (90.9 to 97.1)	59.0 (28.7 to 82.1)	NA	402 (376 to 433)
High	90.1 (85.3 to 94.6)	68.9 (40.6 to 92.6)	NA	388 (358 to 417)
Auto	97.7 (96.2 to 98.4)	39.4 (22.9 to 53.9)	NA	426 (404 to 459)
Belanger et al (2013)[8]	Mean (SD)	Mean (SD)	Mean (SD), %	Mean (SD)
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)

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Study	Sens, %	Spec, %	Accuracy	Total Sleep Time min
Insana et al (2010)[9]	Sens (Range), %	Spec (Range), %	Accuracy (Range), %	
Stages 1 to 2	91.24 (79.6 to 97.9)	NA	NA	NA
Slow wave sleep	96.3 (73.1 to 100)	NA	NA	NA
REM sleep	88.9 (75.4 to 97.9)	NA	NA	NA
Total sleep time	92.4 (79.4 to 97.7)	NA	NA	NA
Wake	NA	58.9 (0 to 100)	NA	NA
Total sleep/total wake	NA	NA	89.6 (65.4 to 97.7)	NA

*Sensitivity, specificity, and accuracy values of epoch-by-epoch comparisons between actigraphy and polysomnography.
ACT: activity count threshold; IQR: interquartile range: NA: not applicable; REM: rapid eye movement; SD: standard deviation; Sens: sensitivity; Spec: specificity.

Actigraphy versus 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.[11] 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).[12] A total of 290 adolescents (age range, 13 to 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 the 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.

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, more effective therapy, or avoid unnecessary therapy or 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.

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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.

A single ancillary study within an RCT, which compared actigraphy with PSG reported that accuracy was 46%.[3] Nonrandomized comparator studies demonstrated low specificity for differentiating sleep-wake patterns.

Section Summary: Children or Adolescents with Sleep-Related Disorders

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.

Central Disorders of Hypersomnolence

Clinical Context and Test Purpose

The purpose of actigraphy is to provide a diagnostic option that is an alternative to or an improvement on existing tests in the assessment of individuals with central disorders of hypersomnolence.

The following PICO was used to select literature to inform this review.

Populations

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.

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. Actigraphy data are 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.

Comparators

The following tests and tools are currently being used to make decisions about central disorders of hypersomnolence: PSG and sleep diaries or logs. Polysomnography 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 individual's record of symptoms.

Outcomes

The general outcomes of interest are test validity and test accuracy. 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 AUC and 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.

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Study Selection Criteria
For the evaluation of clinical validity of actigraphy, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores);
- Included a suitable reference standard;
- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described.

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).

Review of Evidence
Nonrandomized Studies
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.[13] 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%.

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, more effective therapy, or avoid unnecessary therapy or 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 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.

Section Summary: Central Disorders of Hypersomnolence
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 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.

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Insomnia

Clinical Context and Test Purpose

The purpose of actigraphy is to provide a diagnostic option that is an alternative to or an improvement on existing tests in the assessment of individuals with insomnia.

The following PICO was used to select literature to inform this review.

Populations

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.

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. Actigraphy data are 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.

Comparators

The following tests and tools are currently being used to make decisions about insomnia: PSG and sleep diaries or logs. Polysomnography 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 individual's record of symptoms.

Outcomes

The general outcomes of interest are test validity and test accuracy. 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 AUC and 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.

Study Selection Criteria

For the evaluation of clinical validity of actigraphy, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores);
- Included a suitable reference standard;
- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described.

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).

Review of Evidence

Nonrandomized Comparator and Observational Studies

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.[14] 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

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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.

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 ROC curve analysis, sleep diary measurements produced AUC in the high range (0.84 to 0.97), whereas actigraphy performed less well at discriminating between those with insomnia and controls (AUC range, 0.58 to 0.61).

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.[17] 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.

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.[18] 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).

Sivertsen et al (2006) assessed the sensitivity and specificity of actigraphy and PSG in older adults treated for chronic primary insomnia.[19] 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."

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, more effective therapy, or avoid unnecessary therapy or 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.

Actigraphy accurately measured total sleep time but not other measures of sleep patterning.

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Section Summary: Insomnia

Comparisons with PSG have shown that actigraphy has a 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.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Sleep Medicine

The American Academy of Sleep Medicine (2018) published practice guidelines for the use of actigraphy for the evaluation of sleep disorders and circadian rhythm sleep-wake disorders (Table 7).[20]

Table 7. Recommendations for Actigraphy

Condition	Use	Level of Recommendation
Insomnia disorder (adult)	To estimate sleep parameters	Conditional
Insomnia disorder (pediatric)	Assessment of patients	Conditional
Circadian rhythm sleep-wake disorder (adult)	Assessment of patients	Conditional
Circadian rhythm sleep-wake disorder (pediatric)	Assessment of patients	Conditional
Suspected sleep-disordered breathing (adult)	To estimate total sleep time during recording, integrated with home sleep apnea test devices and in the absence of alternative objective measurements of total sleep time	Conditional
Suspected central disorders of hypersomnolence (adult and pediatric)	To monitor total sleep time prior to testing with the Multiple Sleep Latency Test	Conditional
Suspected insufficient sleep syndrome (adult)	To estimate total sleep time	Conditional
Periodic limb movement disorder (adult and pediatric)	Recommendation to not use actigraphy in place of electromyography for diagnosis	Strong

Level of Recommendation: "Strong" recommendation is one that clinicians should follow under most circumstances. "Conditional" recommendation reflects a lower degree of certainty regarding the outcome and appropriateness of the patient-care strategy for all patients.

U.S. Preventive Services Task Force Recommendations

Not applicable.

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Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

No relevant ongoing trials for actigraphy were identified in an April 2025 search of clinictrials.gov.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical findings (i.e., pertinent symptoms and duration)
  - Comorbidities
  - Activity and functional limitations
  - Family history, if applicable
  - Reason for procedure/test/device, when applicable
  - Pertinent past procedural and surgical history
  - Past and present diagnostic testing and results
  - Prior conservative treatments, duration, and response
  - Treatment plan (i.e., surgical intervention)
- Consultation and medical clearance report(s), when applicable
- Radiology report(s) and interpretation (i.e., MRI, CT, discogram)
- Laboratory results
- Other pertinent multidisciplinary notes/reports: (i.e., psychological or psychiatric evaluation, physical therapy, multidisciplinary pain management), when applicable

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

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

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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Effective Date	Action
12/01/2025	New policy.

Definitions of Decision Determinations

Healthcare Services: For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

Medically Necessary or **Medical Necessity** means reasonable and necessary services to protect life, to prevent significant illness or significant disability, or alleviate severe pain through the diagnosis or treatment of disease, illness, or injury, as required under W&I section 14059.5(a) and 22 CCR section 51303(a). Medically Necessary services must include services necessary to achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity.

For Members less than 21 years of age, a service is Medically Necessary if it meets the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) standard of Medical Necessity set forth in 42 USC section 1396d(r)(5), as required by W&I sections 14059.5(b) and 14132(v). Without limitation, Medically Necessary services for Members less than 21 years of age include all services necessary to achieve or maintain age-appropriate growth and development, attain, regain or maintain functional capacity, or improve, support, or maintain the Member's current health condition. Contractor must determine Medical Necessity on a case-by-case basis, taking into account the individual needs of the Child.

Criteria Determining Experimental/Investigational Status
In making a determination that any procedure, treatment, therapy, drug, biological product, facility, equipment, device, or supply is "experimental or investigational" by the Plan, the Plan shall refer to evidence from the national medical community, which may include one or more of the following sources:

1. Evidence from national medical organizations, such as the National Centers of Health Service Research.
2. Peer-reviewed medical and scientific literature.
3. Publications from organizations, such as the American Medical Association (AMA).
4. Professionals, specialists, and experts.
5. Written protocols and consent forms used by the proposed treating facility or other facility administering substantially the same drug, device, or medical treatment.
6. An expert physician panel selected by one of two organizations, the Managed Care Ombudsman Program of the Medical Care Management Corporation or the Department of Managed Health Care.

Feedback

Blue Shield of California Promise Health Plan is interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at www.blueshieldca.com/en/bsp/providers.

For medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Questions regarding the applicability of this policy should be directed to the Blue Shield of California Promise Health Plan Prior Authorization Department at (800) 468-9935, or the Complex Case

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Management Department at (855) 699-5557 (TTY 711) for San Diego County and (800) 605-2556 (TTY 711) for Los Angeles County or visit the provider portal at www.blueshieldca.com/en/bsp/providers.

Disclaimer: Blue Shield of California Promise Health Plan may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield of California Promise Health Plan reserves the right to review and update policies as appropriate.

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