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 policy does not address the use of actigraphy as a component of portable sleep monitoring under CPT codes 95800 or 95806 (see Blue Shield of California Medical Policy: Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome). When used as a component of portable sleep monitoring, actigraphy should not be separately reported.

There is a CPT category I code for this testing:
- **95803**: Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)

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.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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 to measure levels of physical activity. Food and Drug Administration product code: OLV.
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. 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 three days to two 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 “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 pattem, 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).

Actigraphy has been used for more than two 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 patients with circadian sleep-wake rhythm disorders.

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

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

Patients

The relevant population of interest are 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 is generally recorded for periods between three days to two 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. 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. Patients with circadian sleep-wake rhythm disorders are managed by sleep disorder specialists, respiratory therapists, psychiatrists, and primary care providers in an outpatient clinical setting.

Outcomes

The general outcomes of interest are test validity and test accuracy. Measurement of movement (actigraph) is typically three 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.

Study Selection Criteria

Below are selection criteria for studies to assess whether a test is clinically valid.

a. The study population represents the population of interest. Eligibility and selection are described.
b. The test is compared with a credible reference standard.
c. If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
d. Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (e.g., receiver operating characteristic, AUROC, c-statistic, likelihood ratios) may be included but are less informative.
e. Studies should also report reclassification of diagnostic or risk category.

Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires a 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 23 healthy subjects. 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 one-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 awake by PSG that were also scored as awake 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 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.

**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 indicate 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 (RCTs).

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.

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 is to provide a diagnostic option that is an alternative to or an improvement on existing tests in patients with sleep-associated disorders in children and adolescents.

The question addressed in this evidence review is: Does the 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 are individuals with sleep-associated disorders in children and adolescents. 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. Sleep-associated disorders in children and adolescents are managed by sleep disorder specialists, respiratory therapists, psychiatrists, and primary care providers in an outpatient clinical setting.

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. 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
The general outcomes of interest are test validity and test accuracy. Measurement of movement (actigraph) is typically three 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.

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires a 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 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). 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

<table>
<thead>
<tr>
<th>Study</th>
<th>Countries</th>
<th>Sites</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meltzer et al</td>
<td>U.S.,</td>
<td>50</td>
<td>148 (85 male, 63 female) children born preterm</td>
<td>Caffeine</td>
</tr>
</tbody>
</table>

RCT: randomized controlled trials.

Table 2. Summary of Key RCT Results

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

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

The purpose of the study limitations tables (see Tables 3 and 4) is to display notable limitations 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 Limitations

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Duration of Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meltzer et al</td>
<td>3. Study population is unclear</td>
<td>3. Not intervention of interest</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2016)³</td>
<td>4. Study population not representative of intended use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

RCT: randomized controlled trial.

³ 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.

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

³ 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.

³ 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).

³ 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

<table>
<thead>
<tr>
<th>Study</th>
<th>Selectiona</th>
<th>Blindingb</th>
<th>Delivery of Testc</th>
<th>Selective Reportingd</th>
<th>Data Completenesse</th>
<th>Statisticalf</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meltzer et al</td>
<td>3.</td>
<td>Selection not described</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2016)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

- **Selection key**: 1. Selection not described; 2. Selection not random or consecutive (i.e., convenience).
- **Blinding key**: 1. Not blinded to results of reference or other comparator tests.
- **Delivery of Test 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.
- **Selective Reporting key**: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
- **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.
- **Statistical key**: 1. Confidence intervals and/or p values not reported; 2. Comparison with 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 ROC curves, the ability of actigraphy to classify child correctly as having an Apnea-Hypopnea Index of greater than one 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.

**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 (r=0.47) and overestimated wake after sleep onset by 26 minutes (r=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

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Country</th>
<th>Participants</th>
<th>Treatment</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belanger et al (2013)</td>
<td>Cohort</td>
<td>Canada</td>
<td>12 children ages 2-5 y</td>
<td>Actigraphy algorithms</td>
<td>PSG</td>
</tr>
</tbody>
</table>

PSG: polysomnography.

Table 6. Summary of Key Nonrandomized Trial Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Sen, %</th>
<th>Spec, %</th>
<th>Accuracy</th>
<th>Total Sleep Time min</th>
</tr>
</thead>
<tbody>
<tr>
<td>O'Driscoll et al (2010)</td>
<td>82.2</td>
<td>50.9</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Sen, %</th>
<th>Spec, %</th>
<th>Accuracy</th>
<th>Total Sleep Time min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>96.5</td>
<td>39.4</td>
<td>15.5-67.3</td>
<td>424 (397-453)</td>
</tr>
<tr>
<td>Median</td>
<td>93.9</td>
<td>59.0</td>
<td>28.7-82.1</td>
<td>402 (376-433)</td>
</tr>
<tr>
<td>High</td>
<td>90.1</td>
<td>68.9</td>
<td>40.6-92.6</td>
<td>388 (358-417)</td>
</tr>
<tr>
<td>Auto</td>
<td>97.7</td>
<td>39.4</td>
<td>22.9-53.9</td>
<td>426 (404-459)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Sen, %</th>
<th>Spec, %</th>
<th>Accuracy</th>
<th>Total Sleep Time min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belanger et al (2013)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACT40</td>
<td>87.9</td>
<td>500.7</td>
<td>48.2</td>
<td>500.7 (48.2)</td>
</tr>
<tr>
<td>ACT80</td>
<td>93.4</td>
<td>537.3</td>
<td>50.0</td>
<td>537.3 (50.0)</td>
</tr>
<tr>
<td>AlgoSmooth</td>
<td>97.7</td>
<td>565.1</td>
<td>54.0</td>
<td>565.1 (54.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Sen, %</th>
<th>Spec, %</th>
<th>Accuracy</th>
<th>Total Sleep Time min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insana et al (2010)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stages 1-2</td>
<td>91.24</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Slow wave sleep</td>
<td>96.3</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>REM sleep</td>
<td>88.9</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Total sleep time</td>
<td>92.4</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Wake</td>
<td>NA</td>
<td>58.9</td>
<td>0-100</td>
<td>NA</td>
</tr>
<tr>
<td>Total sleep/total wake</td>
<td>NA</td>
<td>89.6</td>
<td>65.4-97.7</td>
<td>NA</td>
</tr>
</tbody>
</table>

IQR: interquartile range; NA: not applicable; REM: rapid eye movement; SD: standard deviation; 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. 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). 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 three hours per night in the absence of any wakening from sleep diaries, suggesting an overestimation of wake in this population. The discrepancy between actigraphy and sleep diary estimates of sleep was greater for boys than for girls, consistent with PSG studies 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.

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 is to provide a diagnostic option that is an alternative to or an improvement on existing tests in patients with central disorders of hypersomnolence. The question addressed in this evidence review is: Does the use of actigraphy in patients with central disorders of hypersomnolence improve the net health outcome?

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

Patients
The relevant population of interest are 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. Patients with central disorders of hypersomnolence are actively managed by neurologists, sleep disorder specialists, psychiatrists and primary care providers in an outpatient clinical setting.

**Comparators**
The following tests and tools are currently being used to make decisions about disorders of hypersomnolence: 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**
The general outcomes of interest are test validity and test accuracy. Measurement of movement (actigraph) is typically three 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.

**Technically Reliable**
Assessment of technical reliability focuses on specific tests and operators and requires a 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. 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 testings 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 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: 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 is to provide a diagnostic option that is an alternative to or an improvement on existing tests in the assessment of patients with insomnia.

The question addressed in this evidence review is: Does the use of actigraphy in the assessment of patients with insomnia improve the net health outcome?

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

**Patients**
The relevant population of interest are 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. Patients with insomnia are actively managed by sleep disorder specialists, psychiatrists, and primary care providers in an outpatient clinical setting.

**Comparators**
The following tests and tools are currently being used to make decisions about patients with insomnia: 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**
The general outcomes of interest are test validity and test accuracy. Measurement of movement (actigraph) is typically three 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.

**Technically Reliable**
Assessment of technical reliability focuses on specific tests and operators and requires a 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. Epoch-by-epoch comparison with PSG showed sensitivity (ability to detect sleep, 97%) and accuracy (86%) during the usual sleep/lights-out period to be high but specificity (ability to detect wake, 33%) was low. As the amount of wake after sleep onset 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. 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. 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. 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). 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 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 (AUC range, 0.58-0.61).

Dick et al (2010) assessed actigraphy with a SOMNO watch 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. 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 (e.g., sleep latency).

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 an RCT. The 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. The 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. The 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 the effects of the technology on health outcomes.

For individuals who have insomnia who receive actigraphy, the evidence includes prospective and retrospective validation studies. The 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 the effects of the technology on health outcomes.

**Supplemental Information**

**Practice Guidelines and Position Statements**

**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 (see Table 7).

**Table 7. Recommendations for Actigraphy**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Use</th>
<th>Level of Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insomnia disorder (adult)</td>
<td>To estimate sleep parameters</td>
<td>Conditional</td>
</tr>
<tr>
<td>Insomnia disorder (pediatric)</td>
<td>Assessment of patients</td>
<td>Conditional</td>
</tr>
<tr>
<td>Circadian rhythm sleep-wake disorder (adult)</td>
<td>Assessment of patients</td>
<td>Conditional</td>
</tr>
<tr>
<td>Circadian rhythm sleep-wake disorder (pediatric)</td>
<td>Assessment of patients</td>
<td>Conditional</td>
</tr>
<tr>
<td>Suspected sleep-disordered breathing (adult)</td>
<td>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</td>
<td>Conditional</td>
</tr>
<tr>
<td>Suspected central disorders of hypersomnolence (adult and pediatric)</td>
<td>To monitor total sleep time prior to testing with the Multiple Sleep Latency Test</td>
<td>Conditional</td>
</tr>
<tr>
<td>Suspected insufficient sleep syndrome (adult)</td>
<td>To estimate total sleep time</td>
<td>Conditional</td>
</tr>
<tr>
<td>Periodic limb movement disorder (adult and pediatric)</td>
<td>Recommendation to not use actigraphy in place of electromyography for diagnosis</td>
<td>Strong</td>
</tr>
</tbody>
</table>

“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.

The American Academy of Sleep Medicine (2008) practice parameters 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.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**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**

A search of ClinicalTrials.gov in April 2019 did not identify any ongoing or unpublished trials that would likely influence this review.
References


Documentation for Clinical Review

- No records required
Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

IE

The following services may be considered investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>95803</td>
<td>Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)</td>
</tr>
<tr>
<td>HCPCS</td>
<td>None</td>
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</tbody>
</table>

Policy History

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

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/26/2009</td>
<td>New Policy Adoption</td>
</tr>
<tr>
<td>01/06/2012</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>08/06/2013</td>
<td>Policy revision without position change. Policy placed on No Further Routine Literature Review status</td>
</tr>
<tr>
<td>05/29/2013</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>02/01/2017</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>11/01/2017</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>08/01/2018</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>08/01/2019</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>08/01/2020</td>
<td>Annual review. Policy statement updated</td>
</tr>
</tbody>
</table>

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

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## Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California 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 contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.