



Louisiana

Actigraphy

Policy # 00330

Original Effective Date: 07/27/2012

Current Effective Date: 08/09/2021

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

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

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

Services Are Considered Investigational

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

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

Policy Guidelines

When used as a component of portable sleep monitoring, actigraphy should not be separately reported.

Background/Overview

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.

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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 (eg, low, medium, high, automatic) can also be adjusted during data analysis. The most commonly used method (digital integration) reflects both acceleration and amplitude of movement.

Data on patient 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).

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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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Numerous actigraphy devices have been cleared for marketing by the U.S. FDA 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/Source

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.

For individuals who have circadian sleep-wake rhythm disorders who receive actigraphy, the evidence includes an ancillary study within a randomized controlled trial. The 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 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

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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 1).

Table 1. Recommendations for Actigraphy

Condition	Use	Level of Recommendation
Insomnia disorder (adult)	To estimate sleep parameters	Conditional

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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

“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

A search of ClinicalTrials.gov in August 2020 did not identify any ongoing or unpublished trials that would likely influence this review.

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06/28/2012 Medical Policy Committee review
07/27/2012 Medical Policy Implementation Committee approval. New policy.
06/27/2013 Medical Policy Committee review
07/17/2013 Medical Policy Implementation Committee approval. No change to coverage.
07/10/2014 Medical Policy Committee review
07/16/2014 Medical Policy Implementation Committee approval. Investigational statement clarified regarding portable sleep monitoring.
06/25/2015 Medical Policy Committee review
07/15/2015 Medical Policy Implementation Committee approval. No change to coverage.
06/30/2016 Medical Policy Committee review
07/20/2016 Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
07/06/2017 Medical Policy Committee review
07/19/2017 Medical Policy Implementation Committee approval. No change to coverage.
07/05/2018 Medical Policy Committee review
07/11/2018 Medical Policy Implementation Committee approval. No change to coverage.
07/03/2019 Medical Policy Committee review
07/18/2019 Medical Policy Implementation Committee approval. No change to coverage.
07/02/2020 Medical Policy Committee review
07/08/2020 Medical Policy Implementation Committee approval. No change to coverage.
07/01/2021 Medical Policy Committee review
07/14/2021 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 07/2022

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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

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

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

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

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1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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