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MEDICAL POLICY – 2.01.73

Actigraphy

BCBSA Ref. Policy:	2.01.73	
Effective Date:	Oct. 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	Sept. 9, 2024	None
Replaces:	N/A	

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EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Actigraphy is the recording of how a body moves. Actigraphy uses a small device that is usually placed on the wrist or ankle. In some cases, the device is placed on a leg to assess restless legs syndrome. It also has been used to try to look at a person's sleep-wake cycles. High quality medical studies do not show that actigraphy works as well as or better than the usual ways of determining sleep-wake cycles. For this reason, actigraphy is considered investigational (unproven).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Actigraphy	**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.** **Note:** This does not include the use of actigraphy as a component of portable sleep monitoring. (see **Related Information**)

Coding

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

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

This policy does not address the use of actigraphy as a component of portable sleep monitoring. When used as a component of portable sleep monitoring, actigraphy should not be separately reported.

Evidence Review

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.

Background

Sleep Disorders

Sleep disorders affect a large percentage of the US population. For example, estimates suggest that 15% to 24% of the US 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 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 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 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.

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

For children and adolescents with sleep-associated disorders 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 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. 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 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. The relevant outcomes are test accuracy and validity. Comparisons with PSG have shown that actigraphy has poor agreement for reporting wake time and can overestimate sleep efficiency. Comparison with sleep diaries has indicated that actigraphy is less effective at differentiating between individuals 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.

Ongoing and Unpublished Clinical Trials

Ongoing or unpublished trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04943562[a]	Evaluation of the Viability of Actigraphy, Wearable EEG Band and Smartphone for Sleep Staging in Comparison with Polysomnography	108	Jan 2025

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US 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 (see **Table 2**).[20]

Table 2. Recommendations for Actigraphy

Condition	Actigraphy for Diagnosis	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

Condition	Actigraphy for Diagnosis	Level of Recommendation
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.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Numerous actigraphy devices have been cleared for marketing by the US 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.

References

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History

Date	Comments
11/11/05	Add policy to Medicine Section - New Policy
06/16/06	Update Scope and Disclaimer - No other changes.
08/08/06	Replace Policy - Policy reviewed with literature search; references added; no change in policy statement.
11/13/07	Replace Policy - Policy reviewed with literature search; references added; no change in policy statement.
01/13/09	Code Update - Code 95803 added, effective 1/1/09.
10/13/09	Replace Policy - Policy reviewed with literature search; references added; no change in policy statement.
05/10/11	Replace Policy - Policy updated with literature review through December 2010; references added and reordered; policy statement unchanged.
04/10/12	Replace policy. Policy updated with literature review through November 2011; references 10 and 12 added and references reordered; some references removed. Policy statement unchanged.
12/4/12	Updated Related Policy title, 2.01.503.
04/16/13	Replace policy. Rationale section updated based on a literature review through January 4, 2013. References 8 and 15 added; others renumbered or removed. Policy statement unchanged.
10/16/13	Update Related Policies. Change title to policy 2.01.503.
05/05/14	Annual Review. Policy updated with literature review through January 6, 2014; references 7, 10, 12, 15, 18, and 25 added; policy statement unchanged. ICD-9 and ICD-10 diagnosis and procedure codes removed; they are not utilized in adjudication.
01/22/15	Update Related Policies. Change title to 2.01.503.
04/24/15	Annual Review. Policy updated with literature review through January 6, 2015. References 11, 16, and 27 added; others renumbered. Policy statement unchanged.
11/20/15	Update Related Policies. Remove 7.01.516.
12/01/16	Annual Review, approved November 8, 2016. Policy reviewed with literature search; No new studies were identified that compared actigraphy with other diagnostic methods; no change in policy statement.
03/01/17	Annual Review, approved February 14, 2017. Policy updated with literature review through November 3, 2016; reference 16 added. Policy statement unchanged.
11/01/17	Interim Review, approved October 19, 2017. Policy updated with literature review through July 21, 2017; no references added. Policy statement unchanged.
01/01/18	Minor update; removed 2.01.503 from Related Policies as it was archived.

Date	Comments
09/01/18	Annual Review, approved August 10, 2018. Policy updated with literature review through April 2018; references 1 and 20 added. Policy statement unchanged.
09/01/19	Annual Review, approved August 6, 2019. Policy updated with literature review through April 2019; reference added. Policy statement unchanged.
12/01/20	Annual Review, approved November 19, 2020. Policy updated through August 14, 2020; reference added. Policy statement unchanged.
09/01/21	Annual Review, approved August 3, 2021. Policy updated through April 15, 2021; no references added. Policy statement unchanged.
08/01/22	Annual Review, approved July 25, 2022. Policy updated through April 27, 2022; no references added. Policy statement unchanged.
09/01/23	Annual Review, approved August 7, 2023. Policy updated through April 21, 2023; reference added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization where appropriate.
10/01/24	Annual Review, approved September 9, 2024. Policy updated through April 24, 2024; no references added. Policy statement unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.