



FEP Medical Policy Manual

FEP 2.01.73 Actigraphy

Annual Effective Policy Date: October 1, 2024

Original Policy Date: December 2011

Related Policies:

2.01.18 - Diagnosis of Obstructive Sleep Apnea Syndrome

Actigraphy

Description

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.

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 (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 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.

OBJECTIVE

The objective of this evidence review is to determine whether the use of actigraphy in the diagnosis of sleep disorders improves the net health outcome.

POLICY STATEMENT

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

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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.

RATIONALE

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.

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.

SUPPLEMENTAL INFORMATION

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 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 (Table 1).²⁰

Table 1. 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.

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.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
June 2012	Replace policy	Policy updated with literature review through March 2012; references added and reordered. Policy statement changed to not medically necessary
June 2013	Replace policy	Policy updated with literature review through January 4, 2013; references 13, 16, 18 and 20 added and references reordered; policy statement unchanged
June 2015	Replace policy	Policy updated with literature review; references 7, 10, 12, 15, 18 and 25 added and reordered; policy statement unchanged, clarification statement added regarding as sole technique used, does not include use of actigraphy as component of portable sleep monitoring.
June 2015	Replace policy	Policy updated with literature review; references 11, 16, 27 added; policy statement unchanged
April 2016	Replace policy	Policy updated with literature review through November 3, 2016; reference 16 added. Policy statement unchanged.
December 2017	Replace policy	Policy updated with literature review through July 21, 2017; no references added. Policy statement unchanged.
September 2018	Replace policy	Policy updated with literature review through April 30, 2018; references 1 and 20 added. Policy statement unchanged.
September 2019	Replace policy	Policy updated with literature review through April 1, 2019; reference added. Policy statement unchanged.
December 2020	Replace policy	Policy updated through August 14, 2020; reference added. Policy statement unchanged.
September 2021	Replace policy	Policy updated through April 15, 2021; no references added. Policy statement unchanged.
September 2022	Replace policy	Policy updated through April 27, 2022; no references added. Policy statement unchanged.
September 2023	Replace policy	Policy updated through April 21, 2023; reference added. Policy statement unchanged.
September 2024	Replace policy	Policy updated through April 24, 2024; no references added; one ongoing clinical trial identified and added to Supplemental Information. Policy statement unchanged.

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