FEP Medical Policy Manual

FEP 2.01.73 Actigraphy

Effective Policy Date: October 1, 2021

Original Policy Date: December 2011

Related Policies:

2.01.18 - Diagnosis and Medical Management 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.[1,]

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

This policy does not address the use of actigraphy as a component of portable sleep monitoring (see evidence review 2.01.18). When used as a component of portable sleep monitoring, actigraphy should not be separately reported.

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, in children and adolescents 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 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).[19,]

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	Conditional

	of alternative objective measurements of total sleep time	
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.

REFERENCES

1. Paquet J, Kawinska A, Carrier J. Wake detection capacity of actigraphy during sleep. Sleep. Oct 2007; 30(10): 1362-9. PMID 17969470
2. Ford ES, Cunningham TJ, Giles WH, et al. Trends in insomnia and excessive daytime sleepiness among U.S. adults from 2002 to 2012. Sleep Med. Mar 2015; 16(3): 372-8. PMID 25747141
3. Meltzer LJ, Wong P, Biggs SN, et al. Validation of Actigraphy in Middle Childhood. Sleep. Jun 01 2016; 39(6): 1219-24. PMID 27091520
4. Yavuz-Kodat E, Reynaud E, Geoffray MM, et al. Validity of Actigraphy Compared to Polysomnography for Sleep Assessment in Children With Autism Spectrum Disorder. Front Psychiatry. 2019; 10: 551. PMID 31428003
5. O'Driscoll DM, Foster AM, Davey MJ, et al. Can actigraphy measure sleep fragmentation in children?. Arch Dis Child. Dec 2010; 95(12): 1031-3. PMID 19850594
6. Hyde M, O'Driscoll DM, Binette S, et al. Validation of actigraphy for determining sleep and wake in children with sleep disordered breathing. J Sleep Res. Jun 2007; 16(2): 213-6. PMID 17542951
7. Belanger ME, Bernier A, Paquet J, et al. Validating actigraphy as a measure of sleep for preschool children. J Clin Sleep Med. Jul 15 2013; 9(7): 701-6. PMID 23853565
8. Insana SP, Gozal D, Montgomery-Downs HE. Invalidity of one actigraphy brand for identifying sleep and wake among infants. Sleep Med. Feb 2010; 11(2): 191-6. PMID 20083430
9. Spruyt K, Gozal D, Dayyat E, et al. Sleep assessments in healthy school-aged children using actigraphy: concordance with polysomnography. J Sleep Res. Mar 2011; 20(1 Pt 2): 223-32. PMID 20629939
10. Werner H, Molinari L, Guyer C, et al. Agreement rates between actigraphy, diary, and questionnaire for children's sleep patterns. Arch Pediatr Adolesc Med. Apr 2008; 162(4): 350-8. PMID 18391144
11. Short MA, Gradisar M, Lack LC, et al. The discrepancy between actigraphic and sleep diary measures of sleep in adolescents. Sleep Med. Apr 2012; 13(4): 378-84. PMID 22437142
12. Louter M, Arends JB, Bloem BR, et al. Actigraphy as a diagnostic aid for REM sleep behavior disorder in Parkinson's disease. BMC Neurol. Apr 06 2014; 14: 76. PMID 24708629
13. Marino M, Li Y, Rueschman MN, et al. Measuring sleep: accuracy, sensitivity, and specificity of wrist actigraphy compared to polysomnography. Sleep. Nov 01 2013; 36(11): 1747-55. PMID 24179309
14. Taibi DM, Landis CA, Vitiello MV. Concordance of polysomnographic and actigraphic measurement of sleep and wake in older women with insomnia. J Clin Sleep Med. Mar 15 2013; 9(3): 217-25. PMID 23493815
15. Levenson JC, Troxel WM, Begley A, et al. A quantitative approach to distinguishing older adults with insomnia from good sleeper controls. J Clin Sleep Med. Feb 01 2013; 9(2): 125-31. PMID 23372464
16. Kaplan KA, Talbot LS, Gruber J, et al. Evaluating sleep in bipolar disorder: comparison between actigraphy, polysomnography, and sleep diary. Bipolar Disord. Dec 2012; 14(8): 870-9. PMID 23167935
17. Dick R, Penzel T, Fietze I, et al. AASM standards of practice compliant validation of actigraphic sleep analysis from SOMNOwatch versus polysomnographic sleep diagnostics shows high conformity also among subjects with sleep disordered breathing. Physiol Meas. Dec 2010; 31(12): 1623-33. PMID 21071830

18. Sivertsen B, Omvik S, Havik OE, et al. A comparison of actigraphy and polysomnography in older adults treated for chronic primary insomnia. Sleep. Oct 2006; 29(10): 1353-8. PMID 17068990
19. Smith MT, McCrae CS, Cheung J, et al. Use of Actigraphy for the Evaluation of Sleep Disorders and Circadian Rhythm Sleep-Wake Disorders: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. Jul 15 2018; 14(7): 1231-1237. PMID 29991437

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.