Actigraphy

Policy # 00330
Original Effective Date: 07/27/2012
Current Effective Date: 10/14/2024

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: 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.

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 3 days to 2 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 (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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration

approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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.

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).

Actigraphy

Policy # 00330
Original Effective Date: 07/27/2012
Current Effective Date: 10/14/2024

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.

Actigraphy

Policy # 00330
Original Effective Date: 07/27/2012
Current Effective Date: 10/14/2024

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
Ongoing or unpublished trials that might influence this review are listed in Table 2.

Table 2. 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.

References

1. 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
2. Paquet J, Kawinska A, Carrier J. Wake detection capacity of actigraphy during sleep. Sleep. Oct 2007; 30(10): 1362-9. PMID 17969470
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. Enomoto M, Kitamura S, Nakazaki K. Validity of an algorithm for determining sleep/wake states using FS-760 in school-aged children. J Physiol Anthropol. Aug 18 2022; 41(1): 29. PMID 35982481
5. 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

6. 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
7. 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
8. Bélanger MÈ, 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
9. 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
10. 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
11. 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
12. 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
13. 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
14. 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
15. 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
16. 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
17. 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
18. 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
19. 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
20. 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

Original Effective Date: 07/27/2012
Current Effective Date: 10/14/2024

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

Actigraphy

Policy # 00330
Original Effective Date: 07/27/2012
Current Effective Date: 10/14/2024

07/14/2021 Medical Policy Implementation Committee approval. No change to coverage.
09/01/2022 Medical Policy Committee review
09/14/2022 Medical Policy Implementation Committee approval. No change to coverage.
09/07/2023 Medical Policy Committee review
09/13/2023 Medical Policy Implementation Committee approval. No change to coverage.
09/05/2024 Medical Policy Committee review
09/11/2024 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 09/2025

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 2023 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.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

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

Actigraphy

Policy # 00330
Original Effective Date: 07/27/2012
Current Effective Date: 10/14/2024

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:
    1. Consultation with 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

Actigraphy

Policy # 00330
Original Effective Date: 07/27/2012
Current Effective Date: 10/14/2024

NOTICE: 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 eligibility for coverage.