

(20173)

<b>Medical Benefit</b>		<b>Effective Date:</b> 04/01/17	<b>Next Review Date:</b> 01/19
<b>Preauthorization</b>	No	<b>Review Dates:</b> 01/17, 01/18	

***This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: • With circadian sleep-wake rhythm disorders	Interventions of interest are: • Actigraphy	Comparators of interest are: • Polysomnography • Sleep journal	Relevant outcomes include: • Test accuracy • Test validity
Individuals: • With central disorders of hypersomnolence	Interventions of interest are: • Actigraphy	Comparators of interest are: • Polysomnography • Sleep journal	Relevant outcomes include: • Test accuracy • Test validity
Individuals: • With insomnia	Interventions of interest are: • Actigraphy	Comparators of interest are: • Polysomnography • Sleep journal	Relevant outcomes include: • Test accuracy • Test validity

### 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. Sleep-wake cycles may be altered in sleep disorders, including insomnia and circadian rhythm sleep disorders. In addition, 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, central disorders of hypersomnolence, or insomnia who receive actigraphy, the evidence includes prospective and retrospective validation studies. Relevant outcomes are test accuracy and validity. The clinical validity of actigraphy depends on the modality to which it is being compared. Comparisons with sleep diaries have shown reasonable correlations for measures of bedtime, sleep onset, and wake time in adults but not in adolescents. The relative and unique contributions of actigraphy and sleep logs in the diagnosis of sleep disorders and measurement of treatment effects remain to be demonstrated. Comparisons with the more resource-intensive polysomnography or behavioral scoring have indicated that, with the appropriate sensitivity threshold, actigraphy has sufficient sensitivity to detect sleep but has poor specificity distinguishing between wake and sleep. The literature has also revealed that the accuracy of actigraphy for differentiating between wake and sleep decreases as the level of sleep disturbance increases. Overall, progress has been made, especially since 2007 when the American Academy of Sleep Medicine made

research recommendations that compared the reliability and validity of different algorithms with the reference standard. Although actigraphy appears to provide reliable measures of sleep onset and wake time in some patient populations, its clinical utility over sleep diaries has not been demonstrated. Moreover, evidence has shown that actigraphy does not provide a reliable measure of sleep efficiency in clinical populations. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Policy

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.

### Background

Actigraphy refers to the assessment of activity patterns (body movement) using devices, typically placed on the wrist or ankle, that 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 (e.g., low, medium, high, automatic) can also be adjusted during data analysis. The digital integration method reflects both acceleration and amplitude of movement; this form of data analysis is most commonly used today.

Data on patient bed times (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 movement-related level of activity and periods of wake. In addition to providing graphic depiction of the activity pattern, 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. In addition, actigraphy is being investigated as a measure of sleep-wake disturbances associated with numerous diseases and disorders.

### 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 to measure levels of physical activity. FDA product code: OLV.

## Related Protocol

Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

---

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Littner M, Kushida CA, Anderson WM, et al. Practice parameters for the role of actigraphy in the study of sleep and circadian rhythms: an update for 2002. *Sleep*. May 1, 2003; 26(3):337-341. PMID 12749556
2. Ancoli-Israel S, Cole R, Alessi C, et al. The role of actigraphy in the study of sleep and circadian rhythms. *Sleep*. May 1, 2003; 26(3):342-392. PMID 12749557
3. Kushida CA, Littner MR, Morgenthaler T, et al. Practice parameters for the indications for polysomnography and related procedures: an update for 2005. *Sleep*. Apr 2005; 28(4):499-521. PMID 16171294
4. Morgenthaler T, Alessi C, Friedman L, et al. Practice parameters for the use of actigraphy in the assessment of sleep and sleep disorders: an update for 2007. *Sleep*. Apr 2007; 30(4):519-529. PMID 17520797
5. Morgenthaler TI, Lee-Chiong T, Alessi C, et al. Practice parameters for the clinical evaluation and treatment of circadian rhythm sleep disorders. An American Academy of Sleep Medicine report. *Sleep*. Nov 2007; 30(11):1445-1459. PMID 18041479
6. Paquet J, Kawinska A, Carrier J. Wake detection capacity of actigraphy during sleep. *Sleep*. Oct 2007; 30(10):1362-1369. PMID 17969470
7. Marino M, Li Y, Rueschman MN, et al. Measuring sleep: accuracy, sensitivity, and specificity of wrist actigraphy compared to polysomnography. *Sleep*. Nov 2013; 36(11):1747-1755. PMID 24179309
8. 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):1353-1358. PMID 17068990
9. 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):870-879. PMID 23167935
10. 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):217-225. PMID 23493815
11. 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
12. 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):1623-1633. PMID 21071830
13. Blackwell T, Ancoli-Israel S, Redline S, et al. Factors that may influence the classification of sleep-wake by wrist actigraphy: the MrOS Sleep Study. *J Clin Sleep Med*. Aug 15 2011; 7(4):357-367. PMID 21897772
14. Plante DT. Leg actigraphy to quantify periodic limb movements of sleep: a systematic review and meta-analysis. *Sleep Med Rev*. Oct 2014; 18(5):425-434. PMID 24726711

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 1 2013; 9(2):125-131. PMID 23372464
16. Meltzer LJ, Wong P, Biggs SN, et al. Validation of actigraphy in middle childhood. *Sleep*. Jun 01 2016; 39(6):1219-1224. PMID 27091520
17. O'Driscoll DM, Foster AM, Davey MJ, et al. Can actigraphy measure sleep fragmentation in children? *Arch Dis Child*. Dec 2010; 95(12):1031-1033. PMID 19850594
18. 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):213-216. PMID 17542951
19. 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):701-706. PMID 23853565
20. 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):191-196. PMID 20083430
21. 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):223-232. PMID 20629939
22. 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):350-358. PMID 18391144
23. 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):378-384. PMID 22437142
24. Sung M, Adamson TM, Horne RS. Validation of actigraphy for determining sleep and wake in preterm infants. *Acta Paediatr*. Jan 2009; 98(1):52-57. PMID 18754828
25. Sitnick SL, Goodlin-Jones BL, Anders TF. The use of actigraphy to study sleep disorders in preschoolers: some concerns about detection of nighttime awakenings. *Sleep*. Mar 2008; 31(3):395-401. PMID 18363316
26. Sadaka Y, Sadeh A, Bradbury L, et al. Validation of actigraphy with continuous video-electroencephalography in children with epilepsy. *Sleep Med*. Sep 2014; 15(9):1075-1081. PMID 24974198
27. Schutte-Rodin S, Broch L, Buysse D, et al. Clinical guideline for the evaluation and management of chronic insomnia in adults. *J Clin Sleep Med*. Oct 15 2008; 4(5):487-504. PMID 18853708