

EFFECTIVE DATE: 12/01/2014

POLICY LAST UPDATED: 11/6/2018

OVERVIEW

Actigraphy refers to the assessment of activity patterns by devices typically placed on the wrist or ankle that record body movement, which is interpreted by computer algorithms as periods of sleep (absence of activity) and wake (activity). Sleep/wake cycles may be altered in sleep disorders including insomnia and circadian rhythm sleep disorders. In addition, actigraphy could potentially be used to assess sleep/wake disturbances associated with numerous other diseases or disorders. Actigraphy might also be used to measure the level of physical activity.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Blue CHiP for Medicare

Actigraphy is considered not covered 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

When used as a component of portable sleep monitoring, actigraphy should not be separately reported.

Commercial Products

Actigraphy is considered not medically necessary 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

When used as a component of portable sleep monitoring, actigraphy should not be separately reported.

MEDICAL CRITERIA

None

BACKGROUND

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.

For individuals who have circadian sleep-wake rhythm disorders who receive actigraphy, the evidence includes an ancillary study within a randomized controlled trial. 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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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 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 the effects of the technology on health outcomes

Regulatory Status

Numerous actigraphy devices have received U.S. Food and Drug Administration (FDA) clearance for marketing through the 510(k) process. Some actigraphy devices are designed and marketed to measure sleep/wake states while others are designed and marketed to measure levels of physical activity. The clinical validity of actigraphy, the assessment of activity patterns by devices typically placed on the wrist or ankle that record body movement, depends, to a large extent, on the modality with which it is being compared.

Overall, progress has been made since the 2007 American Academy of Sleep Medicine (AASM) research recommendations in assessing the reliability and validity of different algorithms in comparison with the reference standard. Although actigraphy appears to provide reliable measures of sleep onset and wake time in some patient populations, the clinical utility of actigraphy over the less expensive sleep diary has not been demonstrated. Moreover, evidence indicates that actigraphy does not provide a reliable measure of sleep efficiency in clinical populations. Evidence to date does not indicate that this technology is as beneficial as the established alternatives. Therefore, actigraphy is considered not medically necessary as it is investigational.

COVERAGE

BlueCHiP for Medicare and Commercial

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage

CODING

Blue CHiP for Medicare and Commercial

The following code is not medically necessary/not covered:

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

RELATED POLICIES

None

PUBLISHED

Provider Update, January 2019

Provider Update, January 2017

Provider Update, April 2015

Provider Update, January 2015

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