POLICY TITLE	ACTIGRAPHY
POLICY NUMBER	MP 2.087

Original Issue Date (Created):	**1/1/2012**
Most Recent Review Date (Revised):	**03/10/2021**
Effective Date:	**7/1/2021**

I. POLICY

Actigraphy is considered **investigational** when used as the sole technique to 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 Guideline section) There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines
This policy does not address the use of actigraphy as a component of portable sleep monitoring. When used as a component of portable sleep monitoring, actigraphy should be reported separately.

***Note:** The monitoring device necessary for this procedure will be provided by the physician conducting the examination.

Cross-references:
MP 2.045 Diagnosis and Medical Management of Obstructive Sleep Apnea

II. PRODUCT VARIATIONS

TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross. Please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO- Refer to FEP Medical Policy Manual MP-2.01.73, Actigraphy. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

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III. DESCRIPTION/BACKGROUND TOP

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 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 “digital integration” method, resulting in different sensitivities. Sensitivity settings (e.g., 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 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. Also, actigraphy is being investigated as a measure of sleep-wake disturbances associated with other diseases and disorders.

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Regulatory Status

Numerous actigraphy devices have been cleared for marketing by the U.S. Food and Drug Administration 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.

IV. RATIONALE

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Summary of Evidence

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 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.

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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.

V. DEFINITIONS

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510 (K) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

APNEA is the cessation of respiration for at least ten (10) seconds.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this

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medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered:

CPT Codes®								
95803								

IX. REFERENCES

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X. POLICY HISTORY

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MP 2.087	**7/26/11 CAC New policy** adopting BCBSA. Information related to Actigraphy was extracted from MP 2.045 Sleep Apnea Syndrome and a new policy was created. Policy statement unchanged.
	1/29/13 CAC Consensus review. References updated. No changes to the policy statements. FEP variation revised to refer to the FEP medical policy manual. Codes reviewed 12/12/12
	1/28/14 CAC Consensus review. No change to policy statements. References updated. Rationale section added.
	1/27/15 CAC Consensus review. No change to the policy statement. References and rationale updated. No coding changes
	1/26/16 CAC Consensus review. No change to the policy statement. References and rationale updated. Coding reviewed.
	11/10/16 Admin Update -Variation reformatting
	1/31/17 – CAC Consensus review. No change to policy statements. References and rationale reviewed. Coding reviewed
	12/1/17 Consensus review. No change to policy statements. References and rationale updated.
	8/28/18 Consensus review. Clarification to the policy statement this policy does not apply to actigraphy used for portable sleep monitoring. Background and references updated. Rationale revised**.**
	6/14/19 Consensus review. No change to policy statements

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	7/1/20 Consensus review. No change to the policy statement. References reviewed/updated. Coding reviewed with no changes. Product variation statement updated.
	03/10/2021- Consensus review. No change to the policy statement. References reviewed/updated. Coding reviewed with no changes.

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