FEP Medical Policy Manual

FEP 2.01.73 Actigraphy

Effective Date: January 15, 2018

Related Policies:
2.01.18 Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome

Actigraphy

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.

FDA 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.

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 when used as a component of portable sleep monitoring (see policy 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).

RATIONALE

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.
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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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Academy of Sleep Medicine
The most recent practice parameters by the American Academy of Sleep Medicine (AASM) were published in 2007 on the use of actigraphy for the assessment of sleep and sleep disorders (including a separate practice parameter on circadian rhythm sleep disorders) (see Table 1).

Table 1. Recommendations for Actigraphy

<table>
<thead>
<tr>
<th>Condition</th>
<th>Actigraphy for Diagnosis</th>
<th>Actigraphy to Measure Treatment Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shift work disorder</td>
<td>Indicated (option)</td>
<td>Indicated (guideline)</td>
</tr>
<tr>
<td>Jet lag disorder</td>
<td>Not routinely indicated (option)</td>
<td>Indicated (guideline)</td>
</tr>
<tr>
<td>Advanced sleep phase disorder</td>
<td>Indicated (guideline)</td>
<td>Indicated (guideline)</td>
</tr>
<tr>
<td>Delayed sleep phase disorder</td>
<td>Indicated (guideline)</td>
<td>Indicated (guideline)</td>
</tr>
<tr>
<td>Free-running disorder</td>
<td>Indicated (option)</td>
<td>Indicated (guideline)</td>
</tr>
<tr>
<td>Irregular sleep-wake rhythm</td>
<td>Indicated (option)</td>
<td>Indicated (guideline)</td>
</tr>
</tbody>
</table>

“Standards” describe a generally accepted patient care strategy, which reflects a high degree of clinical certainty. “Guidelines” reflect a moderate degree of clinical certainty. “Options” imply either inconclusive or conflicting evidence or conflicting expert opinion.

AASM: American Academy of Sleep Medicine.

AASM practice parameters from 2008 on the clinical management of chronic insomnia in adults reference the 2007 practice parameters on actigraphy, stating that actigraphy is indicated as a method (option) to characterize circadian rhythm patterns or sleep disturbances in individuals with insomnia, including insomnia associated with depression.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.
**REFERENCES**


POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td>Policy updated with literature review through March 2012; references added and reordered. Policy statement changed to not medically necessary</td>
</tr>
<tr>
<td>June 2012</td>
<td>Update Policy</td>
<td>Policy updated with literature review through January 4, 2013; references 13, 16, 18 and 20 added and references reordered; policy statement unchanged</td>
</tr>
<tr>
<td>June 2013</td>
<td>Update Policy</td>
<td>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, see Policy Guidelines.</td>
</tr>
<tr>
<td>June 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 11, 16, 27 added; policy statement unchanged.</td>
</tr>
</tbody>
</table>

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