Anthem

Medical Policy

Subject: Wearable Devices for Stress Relief and Management
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Description/Scope

Wearable devices for stress relief are typically worn on the wrist, waist, skin, or clothes to aid wearers in identifying stressful triggers. Stress relief wearables often include biofeedback to help wearers learn to modify their physiologic response and may contain a therapeutic intervention, such as a calming vibration, activated by device-detected physiologic stressful stimuli or devices for audio-visual entrainment (AVE).

Note: Some benefit plans may exclude coverage of consumer wearable devices (such as a smart phone, smart watch, or other personal tracking devices), including any software or applications. Direct to consumer (DTC) applications are generally excluded from benefit plan coverage.

Position Statement

Investigational and Not Medically Necessary:

Wearable devices for management, monitoring or prevention of stress and stress-related conditions are considered**investigational and not medically necessary** for all indications.

Rationale

Published research to date on the reliability and efficacy of wearable devices for stress relief consists of case-series and cohort studies.

In 2017, Betti and colleagues conducted a study to develop and test the ability of a wearable physiological sensors system, based on electrocardiogram (ECG), electrodermal activity (EDA) and electroencephalogram (EEG), to detect stress and to assess whether related physiological changes in signals were associated with changes in salivary cortisol levels (a validated, reliable, and objective biomarker of stress). A total of 15 healthy participants (mean age 40.8 years), wore a set of 3 commercial sensors (Shimmer Sensor and MindWave Mobile EEG headset) to record physiological signs during application of Maastricht Acute Stress Test. Salivary samples were collected throughout the different phases of the test. Correlation analysis showed that the observed changes in physiological features were consistently associated with levels of salivary cortisol (R2=0.714). The clinical utility of these sensors and their impact on meaningful clinical outcomes remains to be established.

In 2019, Can and colleagues collected physiological data over 9 days from 21 participants of an algorithmic programming contest. The event included lectures, contests and free time. By using heart rate activity, skin conductance and accelerometer data, study investigators were able to successfully discriminate contest programming stress, an increased cognitive load (during lecture) and down-time activities by using machine learning methods. This feasibility study suggests that further study is warranted to determine the clinical utility of such measurement tools in identifying and managing stress.

In 2020, Han and colleagues published data from wearable systems that provide objective daily stress measurements based on three physiological measurements obtained using ECG, photoplethysmogram (PPG) (detects blood volume changes in the microvascular bed of tissue) and galvanic skin response (GSR) using Shimmer3 ECG, Shimmer3 GSRþ, and Empatica E4 wearable sensors. Controlled stress assessments were conducted on 17 participants via laboratory-based stress tests consisting of several tasks designed to induce short-term stress. In a smaller subset of participants, investigators also collected physiological data during everyday life along with self-reported stress levels every 30 minutes (n=3). Study results demonstrated 94.55% accuracy in the generalized model for stress detection. This feasibility study with a limited number of participants suggests measurement of physiological signals may reliably predict periods of stress. The clinical utility and efficacy of such data remains to be established.

In 2021, Hickey and colleagues conducted a systematic review which included 21 studies with the aim of critically appraising the most recent smart devices and wearable technologies used to identify depression, anxiety, and stress, as well as critique the physiological processes used to enable their detection. The included articles that assessed stress and anxiety unanimously used heart rate variability (HRV) parameters for detection of anxiety and stress; stress was better detected by HRV and EGG together. The systematic review concluded that average heart rate used by many commercially available smart devices is not as accurate in the detection of stress and anxiety compared with HRV and electrodermal activity.

In 2021, Giorgi and colleagues studied the reliability and capability of two consumer wearable devices (Empatica E4 and Muse 2) in discriminating specific mental states compared to laboratory equipment. Electrooculographic (EOG) (used to investigate eye movements), EDA and PPG signals were acquired from a group of 17 volunteers who were exposed to a variety of scenarios designed to induce different levels of mental workload, stress, and emotional states. The results demonstrated that the parameters computed by the consumer wearable and laboratory sensors were positively and significantly correlated to one another. The impact of these findings on the clinical utility of the devices warrants further investigation.

In 2021, Nguyen and colleagues conducted a randomized controlled trial in 28 children diagnosed with autism spectrum disorder (ASD) to assess whether a wearable, real-time device called the Anxiety Meter improved wearers ability to detect symptoms related to anxiety prompting faster initiation of relaxation techniques (i.e., diaphragmatic breathing). Study participants were taught how to use diaphragmatic breathing over the course of three visits, on the fourth and final visit participants were randomized to receive feedback via the wearable device or not. All participants were prompted to initiate the relaxation technique if they detected stress. The study reported that feedback from the device was associated with increased likelihood of initiating deep breathing in response to anxiety. Study limitations include the small sample size and single visit measurement to assess the efficacy of the intervention. Study authors concluded that a real-time, anxiety symptom detecting wearable device is feasible for improving anxiety management techniques in ASD. Further research is warranted.

In 2022, Lui and colleagues sought to characterize physiological monitoring capabilities of the Apple Watch and the potential implications for behavioral health treatment. A total of 19 validation or comparison studies were identified, most demonstrated that the

Apple Watch could measure heart rate reasonably well but errors in accuracy increased with movement. Heart rate variability measurements were able to detect mild stress. Apple Watch overestimated energy expenditure but provided the most reliable results relative to comparative devices. None of the studies examined sought to validate the efficacy of the Sleep app feature though the accelerometer's ability to detect sleep disturbances was promising. The review authors concluded, that "a lack of methodologically robust and replicated evidence of user benefit … and concerns about personal health information remain key factors that must be addressed to enable broader uptake."

Background/Overview

Stress is defined as a type of change or stimuli that causes physical, emotional, or psychological strain beyond available resources. Physiologic stress is defined as a body's response to the stimuli or change. While everyone experiences stress to some degree, and stress in and of itself is not inherently bad, chronic stress and the body's physiologic response to stressful stimuli are associated with a multitude of disease processes.

In the past year, the American Psychological Association (2021) reported that 3 out of 4 adults self-identified as experiencing 'high' levels of stress. Recently, there has been mounting interest in the utility of wearable monitoring devices to assess stress levels and physiologic responses to stressful stimuli, including audio-visual entrainment (AVE), a technique that emits pulses of light and sound with the aim of altering brainwave patterns. It is theorized that tracking and monitoring levels of stress can increase the wearer's awareness of stressful stimuli as well as provide opportunity for intervention. As such, wearable devices are being explored as a medium for aiding in the development of coping skills to reduce the intensity of physiologic responses with the end-goal of minimizing negative impacts on overall health and quality of life. At this time, research in this area remains in its infancy as manufacturers explore the reliability and efficacy of wearable devices for stress management.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
99199	Unlisted special service, procedure or report [when specified as stress management using wearable devices]
HCPCS	
E1399	Durable medical equipment, miscellaneous [when described as a wearable device for stress relief and management]
ICD-10 Diagnosis	
	All diagnoses, including but not limited to the following:
F43.0-F43.9	Reaction to severe stress, and adjustment disorders
R45.7	State of emotional shock and stress, unspecified
R45.89	Other symptoms and signs involving emotional state
Z56.6	Other physical and mental strain related to work
Z73.3	Stress, not elsewhere classified

References

Peer Reviewed Publications:

1. Betti S, Lova RM, Rovini E, et al. Evaluation of an integrated system of wearable physiological sensors for stress monitoring in working environments by using biological markers. IEEE Trans Biomed Eng. 2018; 65(8):1748-1758.
2. Can YS, Chalabianloo N, Ekiz D, Ersoy C. Continuous stress detection using wearable sensors in real life: algorithmic programming contest case study. Sensors (Basel). 2019; 19(8):1849.
3. Giorgi A, Ronca V, Vozzi A, et al. Wearable technologies for mental workload, stress, and emotional state assessment during working-like tasks: A comparison with laboratory technologies. Sensors (Basel). 2021; 21(7):2332.
4. Han HJ, Labbaf S, Borelli JL, et al. Objective stress monitoring based on wearable sensors in everyday settings. J Med Eng Technol. 2020; 44(4):177-189.
5. Hickey BA, Chalmers T, Newton P, Lin CT, Sibbritt D, McLachlan CS, Clifton-Bligh R, Morley J, Lal S. Smart Devices and Wearable Technologies to Detect and Monitor Mental Health Conditions and Stress: A Systematic Review. Sensors (Basel). 2021; 21(10):3461.
6. Lui GY, Loughnane D, Polley C, et al. The Apple Watch for monitoring mental health-related physiological symptoms: literature review. JMIR Ment Health. 2022; 9(9):e37354.
7. Nguyen J, Cardy RE, Anagnostou E, et al. Examining the effect of a wearable, anxiety detection technology on improving the awareness of anxiety signs in autism spectrum disorder: a pilot randomized controlled trial. Mol Autism. 2021; 12(1):72.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Psychological Association. Stress in America: One Year Later, A New Wave of Pandemic Health Concerns. 2021. Available at: https://www.apa.org/news/press/releases/stress/2021/sia-pandemic-report.pdf. Accessed on September 19, 2023.

Websites for Additional Information

1. American Psychological Association. Wearable devices as therapy tools. 2021. Available at: https://www.apa.org/monitor/2021/09/sidebar-wearable-devices. Accessed on September 19, 2023.

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Apollo Neuro
Apple Watch Series 6
Bellabeat Leaf Jewelry
BioHarness
Cove
Empatica
Fitbit Sense
Flowtime
Mind Alive
MindWave Mobile
Muse 2 headband
Pip
Sensate 2
Thunc

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
	03/14/2024	Revised the Description/Scope, Background/Overview and Index sections to add AVE devices, including Mind Alive.
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Background/Overview and References section.
Reviewed	11/10/2022	MPTAC review. Updated Rationale and References section.
New	11/11/2021	MPTAC review. Initial document development.
